

US3342182 (Prod: Tekton Research- Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:09:07

All time stamps listed in this document are displayed in GMT

US3342182

Form: Participant Creation

Data signed: (b) (4) 13 Mar 2021 15:22:02

Generated On: 09 Jun 2021 17:09:07

[Participant ID](#)

US3342182

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

US3342182

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:22:06

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 15:22:05

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Date of Informed Consent (<i>dd MMM yyyy</i>)	3 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 15:22:06

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	RECURRENT SINUS INFECTIONS
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	THYROID BIOPSY BENIGN
Start date (dd MMM yyyy)	27 AUG 2020
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)	27 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	TOTAL ABDOMINAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Condition	RECURRENT BILATERAL OVARIAN CYSTS (BENIGN)
Start date (dd MMM yyyy)	UN UNK 1992
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:22:06

Generated On: 09 Jun 2021 17:09:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:33 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:33
Height (<i>xxx.x</i>)	164.5 cm
Weight (<i>xxx.x</i>)	71.9 kg
BMI (<i>xxx.x</i>)	26.57034 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:22:06

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*) 3 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*) UN UNK 1995

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:22:06

Generated On: 09 Jun 2021 17:09:07

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

FREQUENTS SHOPS
APPROXIMATELY 3 TIMES PER
WEEK; GOES TO THE MALL

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 15:22:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

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

What was the participant's randomization number? 189822

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Height	ND - Not Done
Weight	ND - Not Done

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

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)	03 SEP 2020
Time of assessment (00:00-23:59)	13:33 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 13:33
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:07
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

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) 03 SEP 2020

What was the treatment time? (00:00-23:59) 14:34 (24 HR)

Treatment Date and Time (derived) 03 SEP 2020 14:34

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

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:22	3 SEP 2020 14:22
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:08

PC Open Date & Time

03 SEP 2020 14:54

PC Close Date & Time

03 SEP 2020 17:24

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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	03 SEP 2020 18:43
PC Open Date & Time	03 SEP 2020 18:19
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

04 SEP 2020 13:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

05 SEP 2020 22:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

07 SEP 2020 22:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

09 SEP 2020 18:31

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:09

PC Open Date & Time

03 SEP 2020 14:54

PC Close Date & Time

03 SEP 2020 17:24

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:43

PC Open Date & Time

03 SEP 2020 18:19

PC Close Date & Time

04 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

04 SEP 2020 13:46

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

05 SEP 2020 22:45

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

06 SEP 2020 20:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

07 SEP 2020 22:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

08 SEP 2020 20:22

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:32

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:09
PC Open Date & Time	03 SEP 2020 14:54
PC Close Date & Time	03 SEP 2020 17:24

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:43
PC Open Date & Time	03 SEP 2020 18:19
PC Close Date & Time	04 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:47
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 3889

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 22:46
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

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EAB) (1725)

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:14
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

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EAB) (1725)

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:10
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:32
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 22:32

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 11 SEP 2020 20:02

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:45

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 22:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 10:14

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:15

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 22:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:54

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 20:33

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 18:43

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 20:13

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 20:57

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 23:16

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 23:15

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 19:54

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 20:09

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 20:27

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 20:52

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:38

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 21:59

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 20:36

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 33

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 34

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 22:32
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 SEP 2020 20:02
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 SEP 2020 20:45
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 SEP 2020 22:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 SEP 2020 10:14
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 21:15
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 SEP 2020 22:15
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 SEP 2020 21:54
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 19
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 SEP 2020 20:33
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 SEP 2020 18:43
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 20:13
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 20:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 23
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 SEP 2020 23:16
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 SEP 2020 23:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 25
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 SEP 2020 19:54
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 26
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 SEP 2020 20:09
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 27
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 20:28
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 28
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 SEP 2020 20:52
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 29
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 OCT 2020 20:38
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 30
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 21:59
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 31
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 32
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 OCT 2020 20:36
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 33
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	14:54 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 14:54
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	16:57 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 16:57
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 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)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 16:21 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 16:21

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

US3342182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

16:12 (24 HR)

Collection date and time (derived)

15 OCT 2020 16:12

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:14	15 OCT 2020 16:14
Nasopharyngeal Swab 2	No		

US3342182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 17:00

PC Open Date & Time

15 OCT 2020 16:41

PC Close Date & Time

15 OCT 2020 19:11

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	15 OCT 2020 21:01
PC Open Date & Time	15 OCT 2020 20:06
PC Close Date & Time	16 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 22:27

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 OCT 2020 22:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

98.3 °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

18 OCT 2020 20:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 21:41

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 21:37

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 22:20

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 17:01

PC Open Date & Time

15 OCT 2020 16:41

PC Close Date & Time

15 OCT 2020 19:11

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

15 OCT 2020 21:02

PC Open Date & Time

15 OCT 2020 20:06

PC Close Date & Time

16 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

16 OCT 2020 22:27

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

17 OCT 2020 22:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

18 OCT 2020 20:51

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

19 OCT 2020 21:41

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

20 OCT 2020 21:37

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

21 OCT 2020 22:20

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 17:01
PC Open Date & Time	15 OCT 2020 16:41
PC Close Date & Time	15 OCT 2020 19:11

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Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 21:02
PC Open Date & Time	15 OCT 2020 20:06
PC Close Date & Time	16 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 ☒

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 22:27
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 ☒

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EAB) (1725)

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US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 22:03
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 20:51
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 21:41
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 21:38
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

		Yes <input type="checkbox"/>
PC Time stamp	21 OCT 2020 22:21	
PC Open Date & Time	21 OCT 2020 12:00	
PC Close Date & Time	22 OCT 2020 11:59	

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 22 OCT 2020 20:35

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 OCT 2020 00:28

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 OCT 2020 20:27

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

PC Time Stamp

25 OCT 2020 20:16

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

PC Time Stamp

26 OCT 2020 20:04

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 14:20

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 20:36
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 00:28
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 OCT 2020 20:27
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 20:16
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	26 OCT 2020 20:04
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 OCT 2020 14:20
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:55

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 15:35
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

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.

US3342182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 NOV 2020
Collection time (00:00-23:59)	16:34 (24 HR)
Collection date and time (derived)	13 NOV 2020 16:34

US3342182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:48:56

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 15:25:51
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 10:16:51

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

19 NOV 2020 13:52:26

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 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	24 NOV 2020 21:51:19
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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	28 NOV 2020 11:24:07
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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	05 DEC 2020 20:56:46
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

12 DEC 2020 22:29:36

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

19 DEC 2020 22:15:51

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

26 DEC 2020 09:46:01

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 00:02:09
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 JAN 2021 12:37:40
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 16:59:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	True
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 JAN 2021 21:00:18
Patient Cloud Open Date & Time	23 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
203 of 3889	

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 16:46:09

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 20:28:43
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 12:46:36
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 22:00:18

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 17:25:54

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 23:10:09

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 10:09:19
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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	22 MAR 2021 16:10:57
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

27 MAR 2021 11:18:28

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

05 APR 2021 12:40:59

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 22:43:15
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

19 APR 2021 16:10:54

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 APR 2021 20:01:36
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

03 MAY 2021 20:50:49

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 250

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

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

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

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

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

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

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 306

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

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

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

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

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

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

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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="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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3342182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:09:07

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		04 MAR 2021 18:31:54

US3342182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

PATIENT WAS COVID (+) WAS
BEING MONITORED VIA DAILY
PHONE CALLS

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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

Visit date (dd MMM yyyy)	01 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 APR 2021
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 13:17
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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.

US3342182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 APR 2021

Collection time (00:00-23:59)

13:49 (24 HR)

Collection date and time (derived)

01 APR 2021 13:49

US3342182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Date of Contact	23 DEC 2020
Time of Contact	13:00
Date and Time of Contact (derived)	23 DEC 2020 13:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 DEC 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)

395 of 3889

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

396 of 3889

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99 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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Symptom Day

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 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"/>
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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
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Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

Date	29 DEC 2020
------	-------------

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

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

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
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Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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	3 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		455 of 3889
EAB) (1725)		

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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	4 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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"/>
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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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	5 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		463 of 3889
EAB) (1725)		

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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	6 JAN 2021
------	------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	100.9 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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	7 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 13 Mar 2021 15:22:03

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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 checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (21)

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	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	8 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 13 Mar 2021 15:22:03

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

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Form: Symptom Log (21)

Data signed: (b) (4) 13 Mar 2021 15:22:03

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

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Form: Symptom Log (22)

Data signed: (b) (4) 13 Mar 2021 15:22:03

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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 checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (22)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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"/>

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

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Form: Symptom Log (23)

Data signed: (b) (4) 13 Mar 2021 15:22:03

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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 checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (23)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 JAN 2021
------	-------------

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

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

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

Temperature	101.3 F
-------------	---------

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

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

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

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

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Generated On: 09 Jun 2021 17:09:07

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

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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 ☐

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (24)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	100.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	99.7 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)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 JAN 2021
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.1 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.2 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Apr 2021 15:37:06

Generated On: 09 Jun 2021 17:09:07

Date of Visit	12 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	12 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input checked="" 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

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:37:27

Generated On: 09 Jun 2021 17:09:07

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 _____

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:37:27

Generated On: 09 Jun 2021 17:09:07

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

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 16:37:27

Generated On: 09 Jun 2021 17:09:07

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment 17 JAN 2021

Radiographical Evidence Yes ☒
No ☐

Date of Assessment 17 JAN 2021

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

Start Date

End Date

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Date of Contact	23 DEC 2020
Time of Contact	13:00
Date and Time of Contact (derived)	23 DEC 2020 13:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Date of Visit	23 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	23 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 DEC 2020
Day 5	Yes	27 DEC 2020
Day 7	Yes	29 DEC 2020
Day 9	Yes	31 DEC 2020
Day 14	Yes	5 JAN 2021
Day 21	Yes	12 JAN 2021
Day 28	Yes	19 JAN 2021

US3342182

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 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

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 DEC 2020
Time of assessment (00:00-23:59)	13:20 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 13:20
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342182

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

US3342182

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 DEC 2020

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:22
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3342182

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 JAN 2021

US3342182

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

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

Visit date (dd MMM yyyy)	2 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3342182

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

Form: Unblinding

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Date of updated informed consent (<i>dd MMM yyyy</i>)	2 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>)	2 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3342182

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3342182

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 13:36
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	16:58 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 16:58
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

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

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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.

US3342182

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

Form: Exposure

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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) 03 MAR 2021

What was the treatment time? (00:00-23:59) 16:28 (24 HR)

Treatment Date and Time (derived) 03 MAR 2021 16:28

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

US3342182

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 MAR 2021

Collection time (00:00-23:59)

16:03 (24 HR)

Collection date and time (derived)

03 MAR 2021 16:03

US3342182

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00 - 23:59)	16:04
Collection Date and Time (derived)	03 MAR 2021 16:04

US3342182

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

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 15:22:05

Generated On: 09 Jun 2021 17:09:07

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

US3342182

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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)	01 APR 2021
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 13:17
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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)	01 APR 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	01 APR 2021 14:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3342182

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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.

US3342182

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

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) 01 APR 2021

What was the treatment time? (00:00-23:59) 14:13 (24 HR)

Treatment Date and Time (derived) 01 APR 2021 14:13

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

US3342182

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:37:06

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342182

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342182

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 15:50:31

Generated On: 09 Jun 2021 17:09:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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 _____

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

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	
Height (derived)	
Weight (derived)	

US3342182

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3342182

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 23:37:28

Generated On: 09 Jun 2021 17:09:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

AEID

Adverse event

MEDICATION INDUCED
HEADACHE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

PATIENT WAS WRONGLY
PRESCRIBED 20 MG OF
LEXAPRO IN LIEU OF THE
NORMALLY PRESCRIBED 20 MG
OF CITALOPRAM STARTING ON
18 SEP 2020. PATIENT HAS
STATED THEY ARE
EXPERIENCING EXACERBATED
HEADACHES FOLLOWING THE
FIRST VACCINATION BUT
ATTRIBUTES THE
CONTINUATION OF THIS
SYMPTOM TO THE CHANGE IN
MEDICATION.

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)	

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

AEID	
Adverse event	GENERALIZED ANXIETY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

AEID

Adverse event

HEADACHE
POST-VACCINATION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

15:07 (24 HR)

AE start date and time (derived)

03 SEP 2020 15:07

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 SEP 2020

End time (00:00-23:59)

10:00 (24 HR)

AE End Date and Time (derived)

17 SEP 2020 10:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

AEID	USA-US203-2021-MRNA-1273-P30 1000005
Adverse event	COVID-19 INFECTION
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)	19 DEC 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)	05 FEB 2021
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"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

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 type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

SUBJECT CAME ONSITE ON 23DEC2021 WITH SYMPTOMS OF MODERATE HEADACHE AND DIARRHEA. SUBJECT TESTED + OUTSIDE ON STUDY 06JAN21. SITE RECEIVED NP SWAB RESULTS AND WERE NEGATIVE FROM DAY-ADVISED BY SPONSOR THAT SUBJECT COULD EXIT CONVALESCENT PERIOD 12JAN2021. SITE LATER RECEIVED REPORT FROM SALIVA TEST DAY 21 + RESULT AND SUBJECT RE-ENTERD CONVALESCENT PERIOD. SUBJECT THEN REPORTED FEVER, CHILLS, SOB, FATIGUE, AND BODY ACHES. SUBJECT FOLLOWED UP WITH PCP AND WAS GIVEN PREDNISONE, ALBUTEROL, ONDASTERONM AND AZITHROMYCIN FOR SYMPTOMS. SUBJECT RETURNED TO SITE 19JAN21 WITH SYMPTOMS ONGOING COUGH, SOB, FATIGUE, BODY ACHES, HEADACHE. RESULT FROM D28 SALIVA NEGATIVE. LAST COVID SYMPTOMS RESOLVED ON 05FEB2021

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

AEID	
Adverse event	WORSENING TENSION HEADACHES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	05 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Mar 2021 15:07:06

Generated On: 09 Jun 2021 17:09:07

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

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

Yes ☒

No ☐

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

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 60

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication TRIAMTERENE/HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Mar 2021 15:07:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication GUIFENESIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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 2000	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 2000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☒
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:07:07

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Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

5 TIMES/WEEK

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	01 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:07:07

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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 2000	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 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)	15 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:07:07

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Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED ANXIETY AE

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

QHS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	26 OCT 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication CORTISONE INJECTION

Prophylaxis Yes ☐
No ☒

Indication HEADACHE AE

Dose per administration UNK

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNK

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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 checked="" type="checkbox"/>
If route of administration is Other, specify		CERVICAL EPIDURAL SPACE
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication HIGH DOSE INFLUENZA
VACCINATION.

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intraocular	<input type="radio"/>
	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)	03 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication CITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 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"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION AE

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION AE

Dose per administration 90

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 44

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

2 TIMES/WEEK

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	01 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION AE

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 17 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION AE

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 20 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication ONDASTERON

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19 INFECTION AE

Dose per administration 250

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication TENSION HEADACHES AE

Dose per administration 7.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)		05 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

Name of Medication CYCLOBENZAPRINE HCL

Prophylaxis Yes ☐
No ☒

Indication TENSION HEADACHES AE

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Mar 2021 15:07:07

Generated On: 09 Jun 2021 17:09:07

	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)	05 FEB 2021	
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"/>

US3342182

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Mar 2021 15:22:03

Generated On: 09 Jun 2021 17:09:07

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:09:07

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:09:07

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 ☐

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 29 Mar 2021 15:07:09

Generated On: 09 Jun 2021 17:09:07

SAEID	USA-US203-2021-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Mar 2021 15:07:09

Generated On: 09 Jun 2021 17:09:07

SAEID	USA-US203-2021-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 15:57
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

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Mar 2021 15:07:09

Generated On: 09 Jun 2021 17:09:07

SAEID	USA-US203-2021-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 18:13
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

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Mar 2021 15:07:09

Generated On: 09 Jun 2021 17:09:07

SAEID	USA-US203-2021-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:01
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

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Mar 2021 15:07:09

Generated On: 09 Jun 2021 17:09:07

SAEID	USA-US203-2021-MRNA-1273-P301000005
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	PAUL
Investigator's Last Name	PICKRELL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/MAR/2021 17:00
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

US3342182 (Prod: Tekton Research- Austin)

US3342182

Form: Participant Creation

Generated On: 09 Jun 2021 17:09:07

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:04:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'US3342182'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:49:27

US3342182

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:16

US3342182

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '03 SEP 2020'	RWS_ENDPOINT	03 Sep 2020 18:49:28
	ENDPOINT (b) (4)	

US3342182

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Clinic (Clinic)'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:16

US3342182

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'SCRN'	System	03 Sep 2020 19:34:16

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered (b) (6) 1950'	RWS_ENDPOINT	03 Sep 2020 18:49:29
	ENDPOINT (b) (4)	

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '70'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'YEARS'	System	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '70'	System	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Female (F)'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'I'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:07

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:34:46

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Sep 2020'	System	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2020'	System	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Amendment 3 (3)'	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:35:36

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	RWS_ENDPOINT	03 Sep 2020 18:49:28
	ENDPOINT (b) (4)	

US3342182

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1'	System	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:09:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:33

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:03:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:03:51
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:03:04
User entered 'seasonal allergies'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:02:53

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Bronchial hyperreactivity, LLT: Reactive airways disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:04:07
User entered 'reactive airway disease'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 2010'	System	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2010'	System	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:07

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:04:07
User entered 'recurrent sinus infections'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:28

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:44
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:04:07
User entered 'hyperlipidemia'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:03:42

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Thyroid histopathology procedures, PT: Biopsy thyroid gland, LLT: Thyroid gland biopsy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 16:16:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 16:16:47
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:05:09
User entered 'thyroid biopsy benign'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '27 Aug 2020'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '27 Aug 2020'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Aug 2020'	System	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2020'	System	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Aug 2020'	System	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2020'	System	03 Sep 2020 20:04:11

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:05:09
User entered 'hypothyroidism'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2000'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 2000'	System	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2000'	System	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:04:24

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:05:09
User entered 'hypertension'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1990'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1990'	System	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1990'	System	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:04:36

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 11:36:29
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:54:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total abdominal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:05:45
Data point term sent to Coder	System	03 Sep 2020 20:05:09
User entered 'total abdominal hysterectomy'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:04:56

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Benign ovarian cyst - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:34:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:34:04
User closed query 'Per DM CLR: Please update the condition to confirm if the RECURRENT OVARIAN CYSTS were benign or cancerous, as well as location (Right or Left Ovary). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:19:46
Data point term sent to Coder	System	05 Nov 2020 16:18:42
Query 'Per DM CLR: Please update the condition to confirm if the RECURRENT OVARIAN CYSTS were benign or cancerous, as well as location (Right or Left Ovary). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'MH has been updated.' (Site from DM).	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:18:40
Coding entries removed.	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:18:24
User entered 'RECURRENT BILATERAL OVARIAN CYSTS (BENIGN)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:18:24

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to confirm if the RECURRENT OVARIAN CYSTS were benign or cancerous, as well as location (Right or Left Ovary). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 14:56:01
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Sep 2020 20:06:47
Data point term sent to Coder	System	03 Sep 2020 20:06:12
User entered 'recurrent ovarian cysts'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1992'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1992'	System	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1992'	System	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 1995'	System	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '1995'	System	03 Sep 2020 20:05:16

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:06:12
User entered 'depression'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2000'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 2000'	System	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2000'	System	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:28

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:06:12
User entered 'headaches'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2000'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 2000'	System	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2000'	System	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:42

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:06:47
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:06:12
User entered 'vitamin d deficiency'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'Jan 2010'	System	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '2010'	System	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered empty.	System	03 Sep 2020 20:05:56

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '13:33'	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '3 Sep 2020 13:33'	System	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '164.5' cm	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25
DataPoint set to visible.	System	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '71.9' kg	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25
DataPoint set to visible.	System	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered '26.57034'	System	03 Sep 2020 19:44:25
DataPoint set to visible.	System	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'kg/m2'	System	03 Sep 2020 19:44:25
DataPoint set to visible.	System	03 Sep 2020 19:43:22

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'bpm'	System	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'breaths/min'	System	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'mmHg'	System	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered missing code ND - Not Done.	Stefanie Mott (b) (4)	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User entered 'mmHg'	System	03 Sep 2020 19:44:25

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05

US3342182

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05

US3342182

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:44:32

US3342182

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 19:44:32

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 09:48:31
Query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' answered with 'Participant has been post-menopausal since 1995 and also state that they had a total abdominal hysterectomy due to ovarian cysts in 1995 as well. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 21:13:36
User opened query 'Per DM CLR: If No, what is the reason? = Post-menopausal, however, HYSTERECTOMY is recorded as MedHistory. Please confirm reason and update as appropriate, otherwise provide clarification ensuring the condition is recorded in the MedHistory eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 11:36:32
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	03 Sep 2020 19:48:12
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	03 Sep 2020 19:47:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stefanie Mott (b) (4)	03 Sep 2020 19:48:12
User entered 'UN UNK 1995'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	03 Sep 2020 19:48:12
User entered 'UN UNK 1995' reason for change:	Stefanie Mott (b) (4)	03 Sep 2020 19:48:12
Data Entry Error		
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	03 Sep 2020 19:47:39
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:09:07

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:47:39

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'frequents shops approximately 3 times per week; goes to the mall'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'I'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:31:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:49:37

US3342182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:50

US3342182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '3 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:50

US3342182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Clinic (Clinic)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:50

US3342182

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'VISIT1'	System	03 Sep 2020 19:49:50

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:25

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '189822'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:25

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:25

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

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)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:59

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

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)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:59

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:59

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:59

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:49:59

US3342182

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:07

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 13:20:07
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'answered' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:35:23
User entered 'No (N)'	(b) (4), (b) (6)	17 Dec 2020 19:35:16
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 21:08:32
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:16:20
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:16:19

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Pre-Dose (PREDOSE)'	Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:35:10
Query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' answered with 'Date entered in proper format.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:43:55
User entered '03 Sep 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:43:40
User opened query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:46:09
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '13:33'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '03 Sep 2020 13:33'	System	04 Nov 2020 20:43:40
User entered '3 Sep 2020 13:33'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '99' F	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Oral (Oral)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '64'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'bpm'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '12'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'breaths/min'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '102'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '62'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered missing code ND - Not Done.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Post-Dose (POSTDOSE)'	Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:35:14
Query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' answered with 'Date entered in correct format.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:44:17
User entered '03 Sep 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	04 Nov 2020 20:44:09
User opened query 'Per CDM: Per CCGs, please enter the date of assessment in (DD-MMM-YYYY) format. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 13:46:18
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:56:25
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' answered with 'per protocol, post dose vitals checked 30 minutes after IP Injection.' (Site from DM).	John Luna (b) (4)	09 Sep 2020 22:09:15
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 21:47:03
User entered '15:07'	Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '03 Sep 2020 15:07'	System	04 Nov 2020 20:44:09
User entered '3 Sep 2020 15:07'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '98.6' F	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Oral (Oral)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '57'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'bpm'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '12'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'breaths/min'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '122'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '76'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	03 Sep 2020 20:25:02

US3342182

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:08

US3342182

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:08

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 18:18:00
' (Site from DM).		
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	21 Oct 2020 19:04:15
' answered with '2 digits have been added' (Site from DM).		
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:04:04
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).	(b) (4), (b) (6)	20 Oct 2020 19:10:02
' (Site from DM).		
User entered '3 Sep 2020'	Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '14:34'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '03 Sep 2020 14:34'	System	21 Oct 2020 19:04:04
User entered '3 Sep 2020 14:34'	System	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'ONCE'	System	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:50:44

US3342182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:56

US3342182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '3 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:50:56

US3342182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:18:52
User entered '14:20' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:18:52
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Sep 2020 19:50:56
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:50:56

US3342182

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '3 Sep 2020 14:20'	System	04 Sep 2020 21:18:52
User entered empty.	System	03 Sep 2020 19:50:56

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '3 Sep 2020'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	04 Sep 2020 21:18:59
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 21:18:59
User entered '14:22' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:18:59
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 19:51:05
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '3 Sep 2020 14:22'	System	04 Sep 2020 21:18:59
User entered empty.	System	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered empty.	System	03 Sep 2020 19:51:05

US3342182

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:51:12

US3342182

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	03 Sep 2020 19:51:12

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:07:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '922f93b6-6cfc-4cc4-909c-abdd966ea0c3' User entered 'Yes (Y)'	System	03 Sep 2020 20:08:07
	System	03 Sep 2020 20:08:07

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:07:52', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '922f93b6-6cfc-4cc4-909c-abdd966ea0c3' User entered '98.6'	System	03 Sep 2020 20:08:07
	System	03 Sep 2020 20:08:07

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:07:57', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '922f93b6-6cfc-4cc4-909c-abdd966ea0c3'	System	03 Sep 2020 20:08:07
User entered 'No (N)'	System	03 Sep 2020 20:08:07

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:08:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '922f93b6-6cfc-4cc4-909c-abdd966ea0c3' User entered '03 Sep 2020 15:08'	System	03 Sep 2020 20:08:07
	System	03 Sep 2020 20:08:07

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 14:54'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 17:24'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:42:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8ac9187f-40fc-4ed2-adee-b874897b735d' User entered 'Yes (Y)'	System	03 Sep 2020 23:43:10
	System	03 Sep 2020 23:43:10

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:42:57', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8ac9187f-40fc-4ed2-adee-b874897b735d' User entered '98.0'	System	03 Sep 2020 23:43:10
	System	03 Sep 2020 23:43:10

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8ac9187f-40fc-4ed2-adee-b874897b735d' User entered 'No (N)'	System	03 Sep 2020 23:43:10
	System	03 Sep 2020 23:43:10

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8ac9187f-40fc-4ed2-adee-b874897b735d' User entered '03 Sep 2020 18:43'	System	03 Sep 2020 23:43:10
	System	03 Sep 2020 23:43:10

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 18:19'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 2'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:19', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2324e4b2-cbdc-4af8-bbc4-ccd65053069e' User entered 'Yes (Y)'	System	04 Sep 2020 18:46:34
	System	04 Sep 2020 18:46:34

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2324e4b2-cbdc-4af8-bbc4-ccd65053069e' User entered '98.5'	System	04 Sep 2020 18:46:34
	System	04 Sep 2020 18:46:34

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2324e4b2-cbdc-4af8-bbc4-ccd65053069e' User entered 'No (N)'	System	04 Sep 2020 18:46:34
	System	04 Sep 2020 18:46:34

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2324e4b2-cbdc-4af8-bbc4-ccd65053069e' User entered '04 Sep 2020 13:46'	System	04 Sep 2020 18:46:34
	System	04 Sep 2020 18:46:34

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 3'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f56d9b0f-e8e0-4c1b-bc5f-84fc4aa86122'	System	06 Sep 2020 03:45:35
User entered 'Yes (Y)'	System	06 Sep 2020 03:45:35

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f56d9b0f-e8e0-4c1b-bc5f-84fc4aa86122' User entered '97.5'	System	06 Sep 2020 03:45:35
	System	06 Sep 2020 03:45:35

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f56d9b0f-e8e0-4c1b-bc5f-84fc4aa86122'	System	06 Sep 2020 03:45:35
User entered 'No (N)'	System	06 Sep 2020 03:45:35

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f56d9b0f-e8e0-4c1b-bc5f-84fc4aa86122'	System	06 Sep 2020 03:45:35
User entered '05 Sep 2020 22:45'	System	06 Sep 2020 03:45:35

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 4'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:25', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cb42c254-f3a2-4f67-a118-d0605e4f4f64' User entered 'Yes (Y)'	System	07 Sep 2020 01:13:42
	System	07 Sep 2020 01:13:42

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cb42c254-f3a2-4f67-a118-d0605e4f4f64' User entered '97.8'	System	07 Sep 2020 01:13:42
	System	07 Sep 2020 01:13:42

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cb42c254-f3a2-4f67-a118-d0605e4f4f64' User entered 'No (N)'	System	07 Sep 2020 01:13:42
	System	07 Sep 2020 01:13:42

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cb42c254-f3a2-4f67-a118-d0605e4f4f64' User entered '06 Sep 2020 20:13'	System	07 Sep 2020 01:13:42
	System	07 Sep 2020 01:13:42

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 5'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c6ea8cc2-ad85-4cda-880e-300799330516' User entered 'Yes (Y)'	System	08 Sep 2020 03:09:27
	System	08 Sep 2020 03:09:27

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c6ea8cc2-ad85-4cda-880e-300799330516' User entered '98.5'	System	08 Sep 2020 03:09:27
	System	08 Sep 2020 03:09:27

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c6ea8cc2-ad85-4cda-880e-300799330516' User entered 'No (N)'	System	08 Sep 2020 03:09:27
	System	08 Sep 2020 03:09:27

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c6ea8cc2-ad85-4cda-880e-300799330516' User entered '07 Sep 2020 22:09'	System	08 Sep 2020 03:09:27
	System	08 Sep 2020 03:09:27

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 6'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:21:29', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '64e71280-2523-4a7a-8656-e790a825c7dd' User entered 'Yes (Y)'	System	09 Sep 2020 01:22:04
	System	09 Sep 2020 01:22:04

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:21:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '64e71280-2523-4a7a-8656-e790a825c7dd' User entered '97.9'	System	09 Sep 2020 01:22:04
	System	09 Sep 2020 01:22:04

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:21:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '64e71280-2523-4a7a-8656-e790a825c7dd'	System	09 Sep 2020 01:22:04
User entered 'No (N)'	System	09 Sep 2020 01:22:04

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '64e71280-2523-4a7a-8656-e790a825c7dd' User entered '08 Sep 2020 20:22'	System	09 Sep 2020 01:22:04
	System	09 Sep 2020 01:22:04

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 7'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:31:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '70582305-be45-476f-a57a-2074ccb6646b' User entered 'Yes (Y)'	System	09 Sep 2020 23:32:05
	System	09 Sep 2020 23:32:05

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:31:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '70582305-be45-476f-a57a-2074ccb6646b' User entered '97.5'	System	09 Sep 2020 23:32:05
	System	09 Sep 2020 23:32:05

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:31:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '70582305-be45-476f-a57a-2074ccb6646b' User entered 'No (N)'	System	09 Sep 2020 23:32:05
	System	09 Sep 2020 23:32:05

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:31:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '70582305-be45-476f-a57a-2074ccb6646b' User entered '09 Sep 2020 18:31'	System	09 Sep 2020 23:32:05
	System	09 Sep 2020 23:32:05

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:08:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '933d8f7b-0737-4408-9d78-d3d9eeaf34d5'	System	03 Sep 2020 20:09:15
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 20:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:08:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '933d8f7b-0737-4408-9d78-d3d9eeaf34d5' User entered 'No (N)'	System	03 Sep 2020 20:09:15
	System	03 Sep 2020 20:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:08:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '933d8f7b-0737-4408-9d78-d3d9eeaf34d5' User entered 'No (N)'	System	03 Sep 2020 20:09:15
	System	03 Sep 2020 20:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '933d8f7b-0737-4408-9d78-d3d9eeaf34d5'	System	03 Sep 2020 20:09:15
User entered 'None (1)'	System	03 Sep 2020 20:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '933d8f7b-0737-4408-9d78-d3d9eeaf34d5' User entered '03 Sep 2020 15:09'	System	03 Sep 2020 20:09:15
	System	03 Sep 2020 20:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 14:54'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 17:24'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '07fb533a-b095-4a50-b53c-23ea539a4e6f' User entered 'None (1)'	System	03 Sep 2020 23:43:29
	System	03 Sep 2020 23:43:29

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '07fb533a-b095-4a50-b53c-23ea539a4e6f' User entered 'No (N)'	System	03 Sep 2020 23:43:29
	System	03 Sep 2020 23:43:29

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:19', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '07fb533a-b095-4a50-b53c-23ea539a4e6f' User entered 'No (N)'	System	03 Sep 2020 23:43:29
	System	03 Sep 2020 23:43:29

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '07fb533a-b095-4a50-b53c-23ea539a4e6f' User entered 'None (1)'	System	03 Sep 2020 23:43:29
	System	03 Sep 2020 23:43:29

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '07fb533a-b095-4a50-b53c-23ea539a4e6f' User entered '03 Sep 2020 18:43'	System	03 Sep 2020 23:43:29
	System	03 Sep 2020 23:43:29

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 18:19'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 2'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bb87ff8c-716b-4235-af42-959989629afb' User entered 'None (1)'	System	04 Sep 2020 18:46:55
	System	04 Sep 2020 18:46:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bb87ff8c-716b-4235-af42-959989629afb' User entered 'No (N)'	System	04 Sep 2020 18:46:55
	System	04 Sep 2020 18:46:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bb87ff8c-716b-4235-af42-959989629afb' User entered 'No (N)'	System	04 Sep 2020 18:46:55
	System	04 Sep 2020 18:46:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bb87ff8c-716b-4235-af42-959989629afb' User entered 'None (1)'	System	04 Sep 2020 18:46:55
	System	04 Sep 2020 18:46:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:54', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bb87ff8c-716b-4235-af42-959989629afb' User entered '04 Sep 2020 13:46'	System	04 Sep 2020 18:46:55
	System	04 Sep 2020 18:46:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 3'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c31c612a-8b8e-41e6-8d6d-f7794f6917f2'	System	06 Sep 2020 03:45:55
User entered 'None (1)'	System	06 Sep 2020 03:45:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c31c612a-8b8e-41e6-8d6d-f7794f6917f2'	System	06 Sep 2020 03:45:55
User entered 'No (N)'	System	06 Sep 2020 03:45:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c31c612a-8b8e-41e6-8d6d-f7794f6917f2' User entered 'No (N)'	System	06 Sep 2020 03:45:55
	System	06 Sep 2020 03:45:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c31c612a-8b8e-41e6-8d6d-f7794f6917f2'	System	06 Sep 2020 03:45:55
User entered 'None (1)'	System	06 Sep 2020 03:45:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c31c612a-8b8e-41e6-8d6d-f7794f6917f2'	System	06 Sep 2020 03:45:55
User entered '05 Sep 2020 22:45'	System	06 Sep 2020 03:45:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 4'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:42', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '805b082b-908c-4d5b-8619-e2b5f16a5276'	System	07 Sep 2020 01:13:55
User entered 'None (1)'	System	07 Sep 2020 01:13:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '805b082b-908c-4d5b-8619-e2b5f16a5276' User entered 'No (N)'	System	07 Sep 2020 01:13:55
	System	07 Sep 2020 01:13:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:48', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '805b082b-908c-4d5b-8619-e2b5f16a5276' User entered 'No (N)'	System	07 Sep 2020 01:13:55
	System	07 Sep 2020 01:13:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '805b082b-908c-4d5b-8619-e2b5f16a5276' User entered 'None (1)'	System	07 Sep 2020 01:13:55
	System	07 Sep 2020 01:13:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:13:54', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '805b082b-908c-4d5b-8619-e2b5f16a5276' User entered '06 Sep 2020 20:13'	System	07 Sep 2020 01:13:55
	System	07 Sep 2020 01:13:55

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 5'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7308f55c-8829-4710-8b7f-614ed0726c83'	System	08 Sep 2020 03:09:42
User entered 'None (1)'	System	08 Sep 2020 03:09:42

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7308f55c-8829-4710-8b7f-614ed0726c83'	System	08 Sep 2020 03:09:42
User entered 'No (N)'	System	08 Sep 2020 03:09:42

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7308f55c-8829-4710-8b7f-614ed0726c83'	System	08 Sep 2020 03:09:42
User entered 'No (N)'	System	08 Sep 2020 03:09:42

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7308f55c-8829-4710-8b7f-614ed0726c83'	System	08 Sep 2020 03:09:42
User entered 'None (1)'	System	08 Sep 2020 03:09:42

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7308f55c-8829-4710-8b7f-614ed0726c83'	System	08 Sep 2020 03:09:42
User entered '07 Sep 2020 22:09'	System	08 Sep 2020 03:09:42

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 6'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '511575e3-8941-4c34-8fc2-d73da9bcbcd1' User entered 'None (1)'	System	09 Sep 2020 01:22:17
	System	09 Sep 2020 01:22:17

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:08', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '511575e3-8941-4c34-8fc2-d73da9bcbcd1' User entered 'No (N)'	System	09 Sep 2020 01:22:17
	System	09 Sep 2020 01:22:17

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '511575e3-8941-4c34-8fc2-d73da9bcbcd1' User entered 'No (N)'	System	09 Sep 2020 01:22:17
	System	09 Sep 2020 01:22:17

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '511575e3-8941-4c34-8fc2-d73da9bcbcd1' User entered 'None (1)'	System	09 Sep 2020 01:22:17
	System	09 Sep 2020 01:22:17

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-08T20:22:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '511575e3-8941-4c34-8fc2-d73da9bcbcd1' User entered '08 Sep 2020 20:22'	System	09 Sep 2020 01:22:17
	System	09 Sep 2020 01:22:17

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 7'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cce3ff7b-b827-4023-b88e-1219194536e6'	System	09 Sep 2020 23:32:18
User entered 'None (1)'	System	09 Sep 2020 23:32:18

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cce3ff7b-b827-4023-b88e-1219194536e6' User entered 'No (N)'	System	09 Sep 2020 23:32:18
	System	09 Sep 2020 23:32:18

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cce3ff7b-b827-4023-b88e-1219194536e6' User entered 'No (N)'	System	09 Sep 2020 23:32:18
	System	09 Sep 2020 23:32:18

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:13', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cce3ff7b-b827-4023-b88e-1219194536e6'	System	09 Sep 2020 23:32:18
User entered 'None (1)'	System	09 Sep 2020 23:32:18

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cce3ff7b-b827-4023-b88e-1219194536e6' User entered '09 Sep 2020 18:32'	System	09 Sep 2020 23:32:18
	System	09 Sep 2020 23:32:18

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be'	System	03 Sep 2020 20:09:47
User entered 'No interference with activity (1)'	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'None (0)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'None (0)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'None (0)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'None (0)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'None (0)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered 'No (N)'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T15:09:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'adfce94e-2af1-43e9-8504-584acb1fc2be' User entered '03 Sep 2020 15:09'	System	03 Sep 2020 20:09:47
	System	03 Sep 2020 20:09:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 14:54'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 17:24'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19'	System	03 Sep 2020 23:43:58
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'None (0)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'None (0)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'None (0)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'None (0)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'None (0)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered 'No (N)'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-03T18:43:56', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cf9a4cd2-c063-40e4-83d3-a7ebfe73db19' User entered '03 Sep 2020 18:43'	System	03 Sep 2020 23:43:58
	System	03 Sep 2020 23:43:58

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Sep 2020 18:19'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 2'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:46:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'None (0)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered 'No (N)'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-04T13:47:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2780eaec-564b-4159-af6f-63b142948f09' User entered '04 Sep 2020 13:47'	System	04 Sep 2020 18:47:18
	System	04 Sep 2020 18:47:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 3'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:45:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:08', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'None (0)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:13', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered 'No (N)'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-05T22:46:17', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1647e94-3fff-472f-ad83-b9e6c6748879' User entered '05 Sep 2020 22:46'	System	06 Sep 2020 03:46:22
	System	06 Sep 2020 03:46:22

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 4'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'None (0)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered 'No (N)'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-06T20:14:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '012bb586-993f-4c25-816e-b0017d5c7f27' User entered '06 Sep 2020 20:14'	System	07 Sep 2020 01:14:18
	System	07 Sep 2020 01:14:18

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 5'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7'	System	08 Sep 2020 03:10:20
User entered 'No interference with activity (1)'	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:09:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'None (0)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'None (0)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'None (0)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'None (0)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'None (0)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered 'No (N)'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-07T22:10:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '18c5d294-c2ed-4bec-b2ed-29ed55e524f7' User entered '07 Sep 2020 22:10'	System	08 Sep 2020 03:10:20
	System	08 Sep 2020 03:10:20

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 6'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 7'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:25', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98'	System	09 Sep 2020 23:32:47
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered 'None (0)'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:29', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered 'None (0)'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered 'None (0)'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered 'None (0)'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered 'None (0)'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98'	System	09 Sep 2020 23:32:47
User entered 'No (N)'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-09T18:32:45', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7c66c6db-f0c7-43de-9185-848e3ffb8b98' User entered '09 Sep 2020 18:32'	System	09 Sep 2020 23:32:47
	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	09 Sep 2020 23:32:47
User entered 'Day 8'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-10T22:32:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '532af475-3e4f-4ff8-8efb-fa4dcc059b57'	System	11 Sep 2020 03:32:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-10T22:32:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '532af475-3e4f-4ff8-8efb-fa4dcc059b57'	System	11 Sep 2020 03:32:33
User entered '10 Sep 2020 22:32'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	09 Sep 2020 23:32:47
User entered 'Day 9'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-11T20:02:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0ba0ac48-6d19-4921-85fc-1b48d0ca9ded'	System	12 Sep 2020 01:02:46
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-11T20:02:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0ba0ac48-6d19-4921-85fc-1b48d0ca9ded' User entered '11 Sep 2020 20:02'	System	12 Sep 2020 01:02:46
	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	11 Sep 2020 03:32:33
User entered 'Day 10'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-12T20:45:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b9c48719-4b8e-448a-b60f-75b7c5c8d477'	System	13 Sep 2020 01:45:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-12T20:45:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b9c48719-4b8e-448a-b60f-75b7c5c8d477'	System	13 Sep 2020 01:45:08
User entered '12 Sep 2020 20:45'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	12 Sep 2020 01:02:46
User entered 'Day 11'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-13T22:45:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '26ebc6ea-6450-4dea-b31e-6ffae02a6acf' User entered 'No interference with activity (1)'	System	14 Sep 2020 03:45:27
	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-13T22:45:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '26ebc6ea-6450-4dea-b31e-6ffae02a6acf' User entered '13 Sep 2020 22:45'	System	14 Sep 2020 03:45:27
	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	13 Sep 2020 01:45:08
User entered 'Day 12'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	14 Sep 2020 03:45:27
User entered 'Day 13'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-16T10:14:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e94b6654-f2ad-40d1-b597-051ece66f88b'	System	16 Sep 2020 15:14:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-16T10:14:29', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e94b6654-f2ad-40d1-b597-051ece66f88b' User entered '16 Sep 2020 10:14'	System	16 Sep 2020 15:14:30
	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	16 Sep 2020 15:14:30
User entered 'Day 14'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	16 Sep 2020 15:14:30
User entered 'Day 15'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-17T21:15:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c254c9d4-1afc-4f21-9389-73bd4ce4f495'	System	18 Sep 2020 02:15:10
User entered 'No interference with activity (1)'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-17T21:15:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c254c9d4-1afc-4f21-9389-73bd4ce4f495'	System	18 Sep 2020 02:15:10
User entered '17 Sep 2020 21:15'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	18 Sep 2020 02:15:10
User entered 'Day 16'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-18T22:15:42', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b8f0a29e-0a54-45af-8188-0911a7aeb19f' User entered 'No interference with activity (1)'	System	19 Sep 2020 03:15:51
	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-18T22:15:45', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b8f0a29e-0a54-45af-8188-0911a7aeb19f' User entered '18 Sep 2020 22:15'	System	19 Sep 2020 03:15:51
	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	18 Sep 2020 02:15:10
User entered 'Day 17'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-19T21:54:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '45fb81bd-e27b-4c74-812f-b331bdbdd309'	System	20 Sep 2020 02:54:28
User entered 'No interference with activity (1)'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-19T21:54:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '45fb81bd-e27b-4c74-812f-b331bdbdd309' User entered '19 Sep 2020 21:54'	System	20 Sep 2020 02:54:28
	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	19 Sep 2020 03:15:51
User entered 'Day 18'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	20 Sep 2020 02:54:28
User entered 'Day 19'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-21T20:33:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f8d90033-6fc3-4fcb-8456-bf9a1df5285e'	System	22 Sep 2020 01:33:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-21T20:33:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f8d90033-6fc3-4fcb-8456-bf9a1df5285e' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 01:33:49
	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 01:33:49
User entered 'Day 20'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-22T18:43:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c8ca50f6-f4eb-4a9e-b7fa-6cc1e1dde9ab'	System	22 Sep 2020 23:43:34
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-22T18:43:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c8ca50f6-f4eb-4a9e-b7fa-6cc1e1dde9ab' User entered '22 Sep 2020 18:43'	System	22 Sep 2020 23:43:34
	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Sep 2020 12:00'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 01:33:49
User entered 'Day 21'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-23T20:13:18', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9bdf777e-377a-4934-bd9e-c930788bd1e8'	System	24 Sep 2020 01:13:23
User entered 'No interference with activity (1)'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-23T20:13:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9bdf777e-377a-4934-bd9e-c930788bd1e8' User entered '23 Sep 2020 20:13'	System	24 Sep 2020 01:13:23
	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 23:43:34
User entered 'Day 22'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-24T20:57:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ad744644-eaf6-4988-967e-9b0ee8e5d392'	System	25 Sep 2020 01:57:39
User entered 'No interference with activity (1)'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-24T20:57:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ad744644-eaf6-4988-967e-9b0ee8e5d392' User entered '24 Sep 2020 20:57'	System	25 Sep 2020 01:57:39
	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	24 Sep 2020 01:13:23
User entered 'Day 23'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-25T23:16:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5027c524-d1cc-4110-bb72-3c75e4418f79'	System	26 Sep 2020 04:16:11
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-25T23:16:08', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5027c524-d1cc-4110-bb72-3c75e4418f79'	System	26 Sep 2020 04:16:11
User entered '25 Sep 2020 23:16'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	25 Sep 2020 01:57:39
User entered 'Day 24'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-26T23:15:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ed8898f1-36aa-434d-8574-b47c29639da5'	System	27 Sep 2020 04:15:20
User entered 'No interference with activity (1)'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-26T23:15:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ed8898f1-36aa-434d-8574-b47c29639da5' User entered '26 Sep 2020 23:15'	System	27 Sep 2020 04:15:20
	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	26 Sep 2020 04:16:11
User entered 'Day 25'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-27T19:54:29', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9adc0eb5-a962-4065-a1bb-3a498997fe37'	System	28 Sep 2020 00:54:37
User entered 'No interference with activity (1)'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-27T19:54:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9adc0eb5-a962-4065-a1bb-3a498997fe37' User entered '27 Sep 2020 19:54'	System	28 Sep 2020 00:54:37
	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	27 Sep 2020 04:15:20
User entered 'Day 26'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-28T20:09:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ea08d77-d165-40b5-9ff3-60768c371d48'	System	29 Sep 2020 01:09:07
User entered 'No interference with activity (1)'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-28T20:09:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ea08d77-d165-40b5-9ff3-60768c371d48' User entered '28 Sep 2020 20:09'	System	29 Sep 2020 01:09:07
	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	28 Sep 2020 00:54:37
User entered 'Day 27'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-29T20:27:56', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4fd5ff61-c5a0-4cd2-afca-66d9848d978b' User entered 'No interference with activity (1)'	System	30 Sep 2020 01:28:00
	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-29T20:27:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4fd5ff61-c5a0-4cd2-afca-66d9848d978b' User entered '29 Sep 2020 20:27'	System	30 Sep 2020 01:28:00
	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	29 Sep 2020 01:09:07
User entered 'Day 28'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-30T20:52:17', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a334dd26-242c-4aa2-985f-2b9bf40aad98'	System	01 Oct 2020 01:52:25
User entered 'No interference with activity (1)'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-30T20:52:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a334dd26-242c-4aa2-985f-2b9bf40aad98'	System	01 Oct 2020 01:52:25
User entered '30 Sep 2020 20:52'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	30 Sep 2020 01:28:00
User entered 'Day 29'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-01T20:38:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c4e36056-5c9d-4bbb-bc86-209f8bb1816f' User entered 'No interference with activity (1)'	System	02 Oct 2020 01:38:48
	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-01T20:38:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c4e36056-5c9d-4bbb-bc86-209f8bb1816f' User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:48
	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	01 Oct 2020 01:52:25
User entered 'Day 30'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-02T21:59:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '14ce1ce4-5721-4bd3-8b93-768a6fc7d18b'	System	03 Oct 2020 02:59:27
User entered 'No interference with activity (1)'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-02T21:59:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '14ce1ce4-5721-4bd3-8b93-768a6fc7d18b' User entered '02 Oct 2020 21:59'	System	03 Oct 2020 02:59:27
	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	02 Oct 2020 01:38:48
User entered 'Day 31'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Oct 2020 02:59:27
User entered 'Day 32'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-04T20:36:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '86135134-9c2e-49e5-89d4-8062540b7d76'	System	05 Oct 2020 01:36:43
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-04T20:36:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '86135134-9c2e-49e5-89d4-8062540b7d76'	System	05 Oct 2020 01:36:43
User entered '04 Oct 2020 20:36'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	05 Oct 2020 01:36:43
User entered 'Day 33'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	05 Oct 2020 01:36:43
User entered 'Day 34'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Headache_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	09 Sep 2020 23:32:47
User entered 'Day 8'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-10T22:32:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1a47bdee-15fe-4995-b02d-13a46bb9c1c3' User entered 'No (N)'	System	11 Sep 2020 03:32:46
	System	11 Sep 2020 03:32:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-10T22:32:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1a47bdee-15fe-4995-b02d-13a46bb9c1c3' User entered '10 Sep 2020 22:32'	System	11 Sep 2020 03:32:46
	System	11 Sep 2020 03:32:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	09 Sep 2020 23:32:47
User entered 'Day 9'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-11T20:02:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '306f85ec-2967-4dca-88cc-0cd10e84cb8a' User entered 'No (N)'	System	12 Sep 2020 01:02:59
	System	12 Sep 2020 01:02:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-11T20:02:55', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '306f85ec-2967-4dca-88cc-0cd10e84cb8a' User entered '11 Sep 2020 20:02'	System	12 Sep 2020 01:02:59
	System	12 Sep 2020 01:02:59

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:32:47

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	11 Sep 2020 03:32:33
User entered 'Day 10'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-12T20:45:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ef0394a7-083e-4b80-8138-9102eb89c077'	System	13 Sep 2020 01:45:16
User entered 'No (N)'	System	13 Sep 2020 01:45:16

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-12T20:45:13', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ef0394a7-083e-4b80-8138-9102eb89c077'	System	13 Sep 2020 01:45:16
User entered '12 Sep 2020 20:45'	System	13 Sep 2020 01:45:16

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 03:32:33

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	12 Sep 2020 01:02:46
User entered 'Day 11'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-13T22:45:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e18a2d26-a9b7-49ac-9653-8a8ce0f29e24' User entered 'No (N)'	System	14 Sep 2020 03:46:53
	System	14 Sep 2020 03:46:53

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-13T22:46:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e18a2d26-a9b7-49ac-9653-8a8ce0f29e24' User entered '13 Sep 2020 22:46'	System	14 Sep 2020 03:46:53
	System	14 Sep 2020 03:46:53

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 01:02:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	13 Sep 2020 01:45:08
User entered 'Day 12'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '14 Sep 2020 12:00'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Sep 2020 11:59'	System	13 Sep 2020 01:45:08

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	14 Sep 2020 03:45:27
User entered 'Day 13'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-16T10:14:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '25f7ddb3-2729-4916-9a3b-10077d8dca25' User entered 'No (N)'	System	16 Sep 2020 15:14:44
	System	16 Sep 2020 15:14:44

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-16T10:14:42', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '25f7ddb3-2729-4916-9a3b-10077d8dca25' User entered '16 Sep 2020 10:14'	System	16 Sep 2020 15:14:44
	System	16 Sep 2020 15:14:44

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 03:45:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	16 Sep 2020 15:14:30
User entered 'Day 14'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	16 Sep 2020 15:14:30
User entered 'Day 15'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-17T21:15:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '16d36832-d02e-47a3-aa5a-4743dab19ded' User entered 'No (N)'	System	18 Sep 2020 02:15:17
	System	18 Sep 2020 02:15:17

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-17T21:15:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '16d36832-d02e-47a3-aa5a-4743dab19ded' User entered '17 Sep 2020 21:15'	System	18 Sep 2020 02:15:17
	System	18 Sep 2020 02:15:17

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:14:30

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	18 Sep 2020 02:15:10
User entered 'Day 16'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-18T22:15:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ede22486-690c-4c5c-bda6-ff5dcb12aae9' User entered 'No (N)'	System	19 Sep 2020 03:15:57
	System	19 Sep 2020 03:15:57

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-18T22:15:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ede22486-690c-4c5c-bda6-ff5dcb12aae9' User entered '18 Sep 2020 22:15'	System	19 Sep 2020 03:15:57
	System	19 Sep 2020 03:15:57

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	18 Sep 2020 02:15:10
User entered 'Day 17'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-19T21:54:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4438808d-1562-455c-a6e5-744f5c827161' User entered 'No (N)'	System	20 Sep 2020 02:54:37
	System	20 Sep 2020 02:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-19T21:54:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4438808d-1562-455c-a6e5-744f5c827161' User entered '19 Sep 2020 21:54'	System	20 Sep 2020 02:54:37
	System	20 Sep 2020 02:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 02:15:10

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	19 Sep 2020 03:15:51
User entered 'Day 18'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 03:15:51

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	20 Sep 2020 02:54:28
User entered 'Day 19'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-21T20:33:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fe5f3e74-7f31-4cf4-85df-0a54c323f45d' User entered 'No (N)'	System	22 Sep 2020 01:33:58
	System	22 Sep 2020 01:33:58

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-21T20:33:54', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fe5f3e74-7f31-4cf4-85df-0a54c323f45d' User entered '21 Sep 2020 20:33'	System	22 Sep 2020 01:33:58
	System	22 Sep 2020 01:33:58

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 02:54:28

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 01:33:49
User entered 'Day 20'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-22T18:43:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cc88714f-8067-4c24-8225-fc88e9148e0c' User entered 'No (N)'	System	22 Sep 2020 23:43:51
	System	22 Sep 2020 23:43:51

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-22T18:43:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cc88714f-8067-4c24-8225-fc88e9148e0c' User entered '22 Sep 2020 18:43'	System	22 Sep 2020 23:43:51
	System	22 Sep 2020 23:43:51

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Sep 2020 12:00'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 01:33:49
User entered 'Day 21'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-23T20:13:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'd3d8a1ea-0c9e-43fa-8e7f-2a708a0d5b14' User entered 'No (N)'	System	24 Sep 2020 01:13:35
	System	24 Sep 2020 01:13:35

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-23T20:13:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'd3d8a1ea-0c9e-43fa-8e7f-2a708a0d5b14'	System	24 Sep 2020 01:13:35
User entered '23 Sep 2020 20:13'	System	24 Sep 2020 01:13:35

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 01:33:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Sep 2020 23:43:34
User entered 'Day 22'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-24T20:57:42', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '282fce42-ef84-411a-98ab-f3152372aa46' User entered 'No (N)'	System	25 Sep 2020 01:57:46
	System	25 Sep 2020 01:57:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-24T20:57:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '282fce42-ef84-411a-98ab-f3152372aa46'	System	25 Sep 2020 01:57:46
User entered '24 Sep 2020 20:57'	System	25 Sep 2020 01:57:46

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 23:43:34

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	24 Sep 2020 01:13:23
User entered 'Day 23'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-25T23:16:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'be6cba7d-203e-4cc4-8419-47d759372cab' User entered 'No (N)'	System	26 Sep 2020 04:16:18
	System	26 Sep 2020 04:16:18

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-25T23:16:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'be6cba7d-203e-4cc4-8419-47d759372cab' User entered '25 Sep 2020 23:16'	System	26 Sep 2020 04:16:18
	System	26 Sep 2020 04:16:18

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:13:23

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	25 Sep 2020 01:57:39
User entered 'Day 24'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-26T23:15:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9f1bac11-6e57-488d-b6fb-47340e24584b' User entered 'No (N)'	System	27 Sep 2020 04:15:27
	System	27 Sep 2020 04:15:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-26T23:15:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9f1bac11-6e57-488d-b6fb-47340e24584b' User entered '26 Sep 2020 23:15'	System	27 Sep 2020 04:15:27
	System	27 Sep 2020 04:15:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:57:39

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	26 Sep 2020 04:16:11
User entered 'Day 25'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-27T19:54:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fb61473d-8c10-4196-8009-9f37a3e24771' User entered 'No (N)'	System	28 Sep 2020 00:54:43
	System	28 Sep 2020 00:54:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-27T19:54:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fb61473d-8c10-4196-8009-9f37a3e24771' User entered '27 Sep 2020 19:54'	System	28 Sep 2020 00:54:43
	System	28 Sep 2020 00:54:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 04:16:11

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	27 Sep 2020 04:15:20
User entered 'Day 26'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-28T20:09:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1d1ac536-4a2d-4b25-81c3-fdcf201d6bf3' User entered 'No (N)'	System	29 Sep 2020 01:09:15
	System	29 Sep 2020 01:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-28T20:09:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1d1ac536-4a2d-4b25-81c3-fdcf201d6bf3' User entered '28 Sep 2020 20:09'	System	29 Sep 2020 01:09:15
	System	29 Sep 2020 01:09:15

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 04:15:20

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	28 Sep 2020 00:54:37
User entered 'Day 27'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-29T20:28:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '640fe330-7325-4f1a-8d7a-8a5ed7216d48' User entered 'No (N)'	System	30 Sep 2020 01:28:07
	System	30 Sep 2020 01:28:07

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-29T20:28:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '640fe330-7325-4f1a-8d7a-8a5ed7216d48' User entered '29 Sep 2020 20:28'	System	30 Sep 2020 01:28:07
	System	30 Sep 2020 01:28:07

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 00:54:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	29 Sep 2020 01:09:07
User entered 'Day 28'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-30T20:52:25', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '3efa4ce4-c078-471d-8d0c-2bc3fcad516d' User entered 'No (N)'	System	01 Oct 2020 01:52:29
	System	01 Oct 2020 01:52:29

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-09-30T20:52:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '3efa4ce4-c078-471d-8d0c-2bc3fcad516d' User entered '30 Sep 2020 20:52'	System	01 Oct 2020 01:52:29
	System	01 Oct 2020 01:52:29

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 01:09:07

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	30 Sep 2020 01:28:00
User entered 'Day 29'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-01T20:38:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bac777ef-e981-4025-9919-cd26e42db8bc' User entered 'No (N)'	System	02 Oct 2020 01:38:54
	System	02 Oct 2020 01:38:54

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-01T20:38:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bac777ef-e981-4025-9919-cd26e42db8bc' User entered '01 Oct 2020 20:38'	System	02 Oct 2020 01:38:54
	System	02 Oct 2020 01:38:54

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 01:28:00

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	01 Oct 2020 01:52:25
User entered 'Day 30'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-02T21:59:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ebe8a450-2536-4b75-a459-3c3e7bfe4d90' User entered 'No (N)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-02T21:59:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ebe8a450-2536-4b75-a459-3c3e7bfe4d90' User entered '02 Oct 2020 21:59'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 01:52:25

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	02 Oct 2020 01:38:48
User entered 'Day 31'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 01:38:48

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Oct 2020 02:59:27
User entered 'Day 32'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-04T20:36:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '758225ea-6870-4e1c-bb20-76369a781959' User entered 'No (N)'	System	05 Oct 2020 01:36:49
	System	05 Oct 2020 01:36:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-04T20:36:48', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '758225ea-6870-4e1c-bb20-76369a781959' User entered '04 Oct 2020 20:36'	System	05 Oct 2020 01:36:49
	System	05 Oct 2020 01:36:49

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 02:59:27

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	05 Oct 2020 01:36:43
User entered 'Day 33'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(33)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	05 Oct 2020 01:36:43
User entered 'Day 34'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 01:36:43

US3342182

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(34)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 01:36:43

US3342182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	10 Sep 2020 21:16:26

US3342182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '10 Sep 2020'	Ethan Shotton (b) (4)	10 Sep 2020 21:16:26

US3342182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	10 Sep 2020 21:16:26

US3342182

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	10 Sep 2020 21:16:26

US3342182

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	10 Sep 2020 21:16:29

US3342182

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	10 Sep 2020 21:16:29

US3342182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	17 Sep 2020 17:20:09

US3342182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '17 Sep 2020'	Ethan Shotton (b) (4)	17 Sep 2020 17:20:09

US3342182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	17 Sep 2020 17:20:09

US3342182

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	17 Sep 2020 17:20:09

US3342182

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	17 Sep 2020 17:20:14

US3342182

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	17 Sep 2020 17:20:14

US3342182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Sep 2020 15:50:27

US3342182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '24 Sep 2020'	Ethan Shotton (b) (4)	24 Sep 2020 15:50:27

US3342182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	24 Sep 2020 15:50:27

US3342182

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	24 Sep 2020 15:50:27

US3342182

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	24 Sep 2020 15:50:31

US3342182

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	24 Sep 2020 15:50:31

US3342182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under V2D29 section. Please update the missing and incomplete pages for this subject following the CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:34:53
Query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under V2D29 section. Please update the missing and incomplete pages for this subject following the CCGs. ' answered with 'Data has been entered into EDC.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	05 Nov 2020 15:50:45
User opened query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under V2D29 section. Please update the missing and incomplete pages for this subject following the CCGs. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:48:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 21:14:03

US3342182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit 2 date is out of window due to lack of lab supplies.' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 20:34:57
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:49:28
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit 2 date is out of window due to lack of lab supplies.' (Site from System).	(b) (4)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	21 Oct 2020 19:04:04
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 13:41:27
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Due to kit shortage patient was unable to receive their second vaccination within window ' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 21:18:02
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Oct 2020 21:14:03
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 21:14:03

US3342182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:14:03

US3342182

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'VISIT2'	System	15 Oct 2020 21:14:03

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '14:54'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '15 Oct 2020 14:54'	System	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '70'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'bpm'	System	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'breaths/min'	System	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '121'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '65'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	15 Oct 2020 21:19:28

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Post-Dose (POSTDOSE)'	Ethan Shotton (b) (4) (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16:57'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '15 Oct 2020 16:57'	System	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '98.7' F	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '62'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'bpm'	System	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'breaths/min'	System	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '122'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '64'	Ethan Shotton (b) (4)	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	15 Oct 2020 22:00:11

US3342182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:37

US3342182

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:37

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16:21'	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '15 Oct 2020 16:21'	System	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Right Arm (RIGHT ARM)'	Ethan Shotton (b) (4)	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'ONCE'	System	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 21:35:33

US3342182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:07

US3342182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:07

US3342182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16:12'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:07

US3342182

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '15 Oct 2020 16:12'	System	05 Nov 2020 15:50:07

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15 Oct 2020'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16:14'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '15 Oct 2020 16:14'	System	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Olivia Hapanowicz (b) (4)	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered empty.	System	05 Nov 2020 15:50:29

US3342182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 21:19:56

US3342182

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	15 Oct 2020 21:19:56

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T16:59:55', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8747f428-ad76-43ee-afc1-1d03fd10ba0e' User entered 'Yes (Y)'	System	15 Oct 2020 22:00:18
	System	15 Oct 2020 22:00:18

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8747f428-ad76-43ee-afc1-1d03fd10ba0e' User entered '98.7'	System	15 Oct 2020 22:00:18
	System	15 Oct 2020 22:00:18

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8747f428-ad76-43ee-afc1-1d03fd10ba0e' User entered 'No (N)'	System	15 Oct 2020 22:00:18
	System	15 Oct 2020 22:00:18

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:13', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8747f428-ad76-43ee-afc1-1d03fd10ba0e' User entered '15 Oct 2020 17:00'	System	15 Oct 2020 22:00:18
	System	15 Oct 2020 22:00:18

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 19:11'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4956ded8-5ff1-4620-bd65-b0b994afd872' User entered 'Yes (Y)'	System	16 Oct 2020 02:01:46
	System	16 Oct 2020 02:01:46

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4956ded8-5ff1-4620-bd65-b0b994afd872' User entered '98.2'	System	16 Oct 2020 02:01:46
	System	16 Oct 2020 02:01:46

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4956ded8-5ff1-4620-bd65-b0b994afd872'	System	16 Oct 2020 02:01:46
User entered 'No (N)'	System	16 Oct 2020 02:01:46

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4956ded8-5ff1-4620-bd65-b0b994afd872' User entered '15 Oct 2020 21:01'	System	16 Oct 2020 02:01:46
	System	16 Oct 2020 02:01:46

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 20:06'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 2'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:26:54', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0cfcaa85-46bb-4aa8-a2f4-c4d048bdb65b' User entered 'Yes (Y)'	System	17 Oct 2020 03:27:12
	System	17 Oct 2020 03:27:12

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0cfcaa85-46bb-4aa8-a2f4-c4d048bdb65b' User entered '97.9'	System	17 Oct 2020 03:27:12
	System	17 Oct 2020 03:27:12

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0cfcaa85-46bb-4aa8-a2f4-c4d048bdb65b' User entered 'No (N)'	System	17 Oct 2020 03:27:12
	System	17 Oct 2020 03:27:12

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0cfcaa85-46bb-4aa8-a2f4-c4d048bdb65b' User entered '16 Oct 2020 22:27'	System	17 Oct 2020 03:27:12
	System	17 Oct 2020 03:27:12

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 3'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:02:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a6e8ae9a-8030-40e5-96ae-9cd3b2f2ba84' User entered 'Yes (Y)'	System	18 Oct 2020 03:03:09
	System	18 Oct 2020 03:03:09

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:02:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a6e8ae9a-8030-40e5-96ae-9cd3b2f2ba84' User entered '97.9'	System	18 Oct 2020 03:03:09
	System	18 Oct 2020 03:03:09

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a6e8ae9a-8030-40e5-96ae-9cd3b2f2ba84' User entered 'No (N)'	System	18 Oct 2020 03:03:09
	System	18 Oct 2020 03:03:09

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a6e8ae9a-8030-40e5-96ae-9cd3b2f2ba84' User entered '17 Oct 2020 22:03'	System	18 Oct 2020 03:03:09
	System	18 Oct 2020 03:03:09

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 4'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1b310313-a4b4-41dd-bf26-39c60ddf8342' User entered 'Yes (Y)'	System	19 Oct 2020 01:51:19
	System	19 Oct 2020 01:51:19

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:08', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1b310313-a4b4-41dd-bf26-39c60ddf8342' User entered '98.3'	System	19 Oct 2020 01:51:19
	System	19 Oct 2020 01:51:19

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1b310313-a4b4-41dd-bf26-39c60ddf8342'	System	19 Oct 2020 01:51:19
User entered 'No (N)'	System	19 Oct 2020 01:51:19

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '1b310313-a4b4-41dd-bf26-39c60ddf8342' User entered '18 Oct 2020 20:51'	System	19 Oct 2020 01:51:19
	System	19 Oct 2020 01:51:19

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 5'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:40:57', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9b8d7034-5030-42e8-b7f1-f32553873d0e' User entered 'Yes (Y)'	System	20 Oct 2020 02:41:21
	System	20 Oct 2020 02:41:21

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9b8d7034-5030-42e8-b7f1-f32553873d0e' User entered '97.9'	System	20 Oct 2020 02:41:21
	System	20 Oct 2020 02:41:21

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9b8d7034-5030-42e8-b7f1-f32553873d0e' User entered 'No (N)'	System	20 Oct 2020 02:41:21
	System	20 Oct 2020 02:41:21

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9b8d7034-5030-42e8-b7f1-f32553873d0e' User entered '19 Oct 2020 21:41'	System	20 Oct 2020 02:41:21
	System	20 Oct 2020 02:41:21

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 6'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:17', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '689b30ab-511e-43ea-808c-711123a8ac3e' User entered 'Yes (Y)'	System	21 Oct 2020 02:37:33
	System	21 Oct 2020 02:37:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '689b30ab-511e-43ea-808c-711123a8ac3e' User entered '97.9'	System	21 Oct 2020 02:37:33
	System	21 Oct 2020 02:37:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '689b30ab-511e-43ea-808c-711123a8ac3e' User entered 'No (N)'	System	21 Oct 2020 02:37:33
	System	21 Oct 2020 02:37:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '689b30ab-511e-43ea-808c-711123a8ac3e' User entered '20 Oct 2020 21:37'	System	21 Oct 2020 02:37:33
	System	21 Oct 2020 02:37:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 7'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f026853a-acd9-4872-a01b-205de0d20bbc' User entered 'Yes (Y)'	System	22 Oct 2020 03:20:27
	System	22 Oct 2020 03:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:18', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f026853a-acd9-4872-a01b-205de0d20bbc' User entered '98.1'	System	22 Oct 2020 03:20:27
	System	22 Oct 2020 03:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f026853a-acd9-4872-a01b-205de0d20bbc' User entered 'No (N)'	System	22 Oct 2020 03:20:27
	System	22 Oct 2020 03:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f026853a-acd9-4872-a01b-205de0d20bbc' User entered '21 Oct 2020 22:20'	System	22 Oct 2020 03:20:27
	System	22 Oct 2020 03:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '351395a2-66e8-4df5-834b-901458106c8b' User entered 'None (1)'	System	15 Oct 2020 22:01:08
	System	15 Oct 2020 22:01:08

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '351395a2-66e8-4df5-834b-901458106c8b' User entered 'No (N)'	System	15 Oct 2020 22:01:08
	System	15 Oct 2020 22:01:08

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:00:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '351395a2-66e8-4df5-834b-901458106c8b' User entered 'No (N)'	System	15 Oct 2020 22:01:08
	System	15 Oct 2020 22:01:08

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '351395a2-66e8-4df5-834b-901458106c8b' User entered 'None (1)'	System	15 Oct 2020 22:01:08
	System	15 Oct 2020 22:01:08

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '351395a2-66e8-4df5-834b-901458106c8b' User entered '15 Oct 2020 17:01'	System	15 Oct 2020 22:01:08
	System	15 Oct 2020 22:01:08

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 19:11'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5e90bb51-a9d7-457f-85d6-aea958bf9b97'	System	16 Oct 2020 02:02:10
User entered 'None (1)'	System	16 Oct 2020 02:02:10

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:54', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5e90bb51-a9d7-457f-85d6-aea958bf9b97'	System	16 Oct 2020 02:02:10
User entered 'No (N)'	System	16 Oct 2020 02:02:10

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:01:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5e90bb51-a9d7-457f-85d6-aea958bf9b97' User entered 'No (N)'	System	16 Oct 2020 02:02:10
	System	16 Oct 2020 02:02:10

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5e90bb51-a9d7-457f-85d6-aea958bf9b97'	System	16 Oct 2020 02:02:10
User entered 'None (1)'	System	16 Oct 2020 02:02:10

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5e90bb51-a9d7-457f-85d6-aea958bf9b97' User entered '15 Oct 2020 21:02'	System	16 Oct 2020 02:02:10
	System	16 Oct 2020 02:02:10

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 20:06'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 2'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cfeb07b4-62fe-42d0-8762-1222628fbfb7'	System	17 Oct 2020 03:27:29
User entered 'None (1)'	System	17 Oct 2020 03:27:29

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:19', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cfeb07b4-62fe-42d0-8762-1222628fbfb7' User entered 'No (N)'	System	17 Oct 2020 03:27:29
	System	17 Oct 2020 03:27:29

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cfeb07b4-62fe-42d0-8762-1222628fbfb7' User entered 'No (N)'	System	17 Oct 2020 03:27:29
	System	17 Oct 2020 03:27:29

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cfef07b4-62fe-42d0-8762-1222628fbfb7'	System	17 Oct 2020 03:27:29
User entered 'None (1)'	System	17 Oct 2020 03:27:29

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'cfeb07b4-62fe-42d0-8762-1222628fbfb7' User entered '16 Oct 2020 22:27'	System	17 Oct 2020 03:27:29
	System	17 Oct 2020 03:27:29

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 3'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:10', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4f396e0c-c0a2-4594-a245-c8fb93044b8b' User entered 'None (1)'	System	18 Oct 2020 03:03:32
	System	18 Oct 2020 03:03:32

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4f396e0c-c0a2-4594-a245-c8fb93044b8b' User entered 'No (N)'	System	18 Oct 2020 03:03:32
	System	18 Oct 2020 03:03:32

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4f396e0c-c0a2-4594-a245-c8fb93044b8b' User entered 'No (N)'	System	18 Oct 2020 03:03:32
	System	18 Oct 2020 03:03:32

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4f396e0c-c0a2-4594-a245-c8fb93044b8b' User entered 'None (1)'	System	18 Oct 2020 03:03:32
	System	18 Oct 2020 03:03:32

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '4f396e0c-c0a2-4594-a245-c8fb93044b8b' User entered '17 Oct 2020 22:03'	System	18 Oct 2020 03:03:32
	System	18 Oct 2020 03:03:32

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 4'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '12373d36-4af2-44d0-b306-48025fb2b8a2'	System	19 Oct 2020 01:51:35
User entered 'None (1)'	System	19 Oct 2020 01:51:35

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '12373d36-4af2-44d0-b306-48025fb2b8a2' User entered 'No (N)'	System	19 Oct 2020 01:51:35
	System	19 Oct 2020 01:51:35

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:25', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '12373d36-4af2-44d0-b306-48025fb2b8a2'	System	19 Oct 2020 01:51:35
User entered 'No (N)'	System	19 Oct 2020 01:51:35

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '12373d36-4af2-44d0-b306-48025fb2b8a2'	System	19 Oct 2020 01:51:35
User entered 'None (1)'	System	19 Oct 2020 01:51:35

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '12373d36-4af2-44d0-b306-48025fb2b8a2'	System	19 Oct 2020 01:51:35
User entered '18 Oct 2020 20:51'	System	19 Oct 2020 01:51:35

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 5'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:17', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'df2a7354-618d-435b-a94d-c2d567298f99'	System	20 Oct 2020 02:41:33
User entered 'None (1)'	System	20 Oct 2020 02:41:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'df2a7354-618d-435b-a94d-c2d567298f99'	System	20 Oct 2020 02:41:33
User entered 'No (N)'	System	20 Oct 2020 02:41:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'df2a7354-618d-435b-a94d-c2d567298f99'	System	20 Oct 2020 02:41:33
User entered 'No (N)'	System	20 Oct 2020 02:41:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'df2a7354-618d-435b-a94d-c2d567298f99'	System	20 Oct 2020 02:41:33
User entered 'None (1)'	System	20 Oct 2020 02:41:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'df2a7354-618d-435b-a94d-c2d567298f99' User entered '19 Oct 2020 21:41'	System	20 Oct 2020 02:41:33
	System	20 Oct 2020 02:41:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 6'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f4b6b1a4-0252-40a4-a924-7bb225f932aa' User entered 'None (1)'	System	21 Oct 2020 02:37:50
	System	21 Oct 2020 02:37:50

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f4b6b1a4-0252-40a4-a924-7bb225f932aa' User entered 'No (N)'	System	21 Oct 2020 02:37:50
	System	21 Oct 2020 02:37:50

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f4b6b1a4-0252-40a4-a924-7bb225f932aa' User entered 'No (N)'	System	21 Oct 2020 02:37:50
	System	21 Oct 2020 02:37:50

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f4b6b1a4-0252-40a4-a924-7bb225f932aa' User entered 'None (1)'	System	21 Oct 2020 02:37:50
	System	21 Oct 2020 02:37:50

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'f4b6b1a4-0252-40a4-a924-7bb225f932aa' User entered '20 Oct 2020 21:37'	System	21 Oct 2020 02:37:50
	System	21 Oct 2020 02:37:50

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 7'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5b789ff3-7013-4bc9-a225-0d8a67c016a0'	System	22 Oct 2020 03:20:45
User entered 'None (1)'	System	22 Oct 2020 03:20:45

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5b789ff3-7013-4bc9-a225-0d8a67c016a0' User entered 'No (N)'	System	22 Oct 2020 03:20:45
	System	22 Oct 2020 03:20:45

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5b789ff3-7013-4bc9-a225-0d8a67c016a0' User entered 'No (N)'	System	22 Oct 2020 03:20:45
	System	22 Oct 2020 03:20:45

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5b789ff3-7013-4bc9-a225-0d8a67c016a0'	System	22 Oct 2020 03:20:45
User entered 'None (1)'	System	22 Oct 2020 03:20:45

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '5b789ff3-7013-4bc9-a225-0d8a67c016a0' User entered '21 Oct 2020 22:20'	System	22 Oct 2020 03:20:45
	System	22 Oct 2020 03:20:45

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:19', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'None (0)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:30', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered 'No (N)'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T17:01:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '518dd186-a437-41a9-80ba-2017ec6992b0' User entered '15 Oct 2020 17:01'	System	15 Oct 2020 22:01:37
	System	15 Oct 2020 22:01:37

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 16:41'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 19:11'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:18', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:21', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'None (0)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered 'No (N)'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-15T21:02:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7ad065c3-f720-42a5-9568-1e7bf7f474c8' User entered '15 Oct 2020 21:02'	System	16 Oct 2020 02:02:39
	System	16 Oct 2020 02:02:39

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '15 Oct 2020 20:06'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 2'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85'	System	17 Oct 2020 03:27:52
User entered 'No interference with activity (1)'	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered 'None (0)'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered 'None (0)'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered 'None (0)'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered 'None (0)'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:45', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered 'None (0)'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85'	System	17 Oct 2020 03:27:52
User entered 'No (N)'	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-16T22:27:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af4f8ec8-2af8-47fc-91c4-718507b5cf85' User entered '16 Oct 2020 22:27'	System	17 Oct 2020 03:27:52
	System	17 Oct 2020 03:27:52

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 3'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2'	System	18 Oct 2020 03:03:56
User entered 'No interference with activity (1)'	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2'	System	18 Oct 2020 03:03:56
User entered 'None (0)'	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2'	System	18 Oct 2020 03:03:56
User entered 'None (0)'	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2' User entered 'None (0)'	System	18 Oct 2020 03:03:56
	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2' User entered 'None (0)'	System	18 Oct 2020 03:03:56
	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2' User entered 'None (0)'	System	18 Oct 2020 03:03:56
	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2'	System	18 Oct 2020 03:03:56
User entered 'No (N)'	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-17T22:03:52', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '92198840-a64e-4dab-93ee-f5d3e1dfe5c2'	System	18 Oct 2020 03:03:56
User entered '17 Oct 2020 22:03'	System	18 Oct 2020 03:03:56

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 4'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0'	System	19 Oct 2020 01:51:58
User entered 'No interference with activity (1)'	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'None (0)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'None (0)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'None (0)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'None (0)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'None (0)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:52', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered 'No (N)'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-18T20:51:56', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '0c2dbd45-3e8c-4867-a5a1-4e7a216b16b0' User entered '18 Oct 2020 20:51'	System	19 Oct 2020 01:51:58
	System	19 Oct 2020 01:51:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 5'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a'	System	20 Oct 2020 02:41:58
User entered 'No interference with activity (1)'	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'None (0)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'None (0)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:45', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'None (0)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:48', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'None (0)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'None (0)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered 'No (N)'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-19T21:41:55', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dcfe6a30-5bef-4de4-a4ac-3fd84b184b0a' User entered '19 Oct 2020 21:41'	System	20 Oct 2020 02:41:58
	System	20 Oct 2020 02:41:58

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 6'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69'	System	21 Oct 2020 02:38:18
User entered 'No interference with activity (1)'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:55', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'None (0)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:57', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'None (0)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:37:59', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'None (0)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:38:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'None (0)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:38:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'None (0)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:38:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered 'No (N)'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-20T21:38:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '556d0c02-14f5-47e2-a654-97bf1b419e69' User entered '20 Oct 2020 21:38'	System	21 Oct 2020 02:38:18
	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	15 Oct 2020 21:35:33
User entered 'Day 7'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223'	System	22 Oct 2020 03:21:17
User entered 'No interference with activity (1)'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'None (0)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'None (0)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:20:57', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'None (0)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:21:02', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'None (0)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:21:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'None (0)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:21:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered 'Yes (Y)'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-21T22:21:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '03f4246e-962c-473b-b646-3796ec5b3223' User entered '21 Oct 2020 22:21'	System	22 Oct 2020 03:21:17
	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 21:35:33

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	21 Oct 2020 02:38:18
User entered 'Day 8'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-22T20:35:49', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9c9be8bf-3e6d-41bf-bc39-d959c276894e'	System	23 Oct 2020 01:35:56
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-22T20:35:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '9c9be8bf-3e6d-41bf-bc39-d959c276894e' User entered '22 Oct 2020 20:35'	System	23 Oct 2020 01:35:56
	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Oct 2020 03:21:17
User entered 'Day 9'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T00:28:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '79204aa7-045f-4e32-900f-9f289277a2dd'	System	24 Oct 2020 05:28:45
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T00:28:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '79204aa7-045f-4e32-900f-9f289277a2dd' User entered '24 Oct 2020 00:28'	System	24 Oct 2020 05:28:45
	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	23 Oct 2020 01:35:56
User entered 'Day 10'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T20:27:25', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6ce680c3-56b6-43d8-8b3b-588d958120df'	System	25 Oct 2020 01:27:32
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T20:27:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6ce680c3-56b6-43d8-8b3b-588d958120df' User entered '24 Oct 2020 20:27'	System	25 Oct 2020 01:27:32
	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	24 Oct 2020 05:28:45
User entered 'Day 11'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-25T20:16:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '701f3304-fe01-4827-9ed3-970b58643430'	System	26 Oct 2020 01:16:36
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-25T20:16:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '701f3304-fe01-4827-9ed3-970b58643430' User entered '25 Oct 2020 20:16'	System	26 Oct 2020 01:16:36
	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	25 Oct 2020 01:27:32
User entered 'Day 12'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-26T20:04:24', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '13163140-9eaf-45b1-ae9b-d46e9d49b91d'	System	27 Oct 2020 01:04:32
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-26T20:04:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '13163140-9eaf-45b1-ae9b-d46e9d49b91d' User entered '26 Oct 2020 20:04'	System	27 Oct 2020 01:04:32
	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	26 Oct 2020 01:16:36
User entered 'Day 13'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	27 Oct 2020 01:04:32
User entered 'Day 14'	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-28T14:20:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dc2b4572-48a7-4574-aa8a-e81401f62c9b' User entered 'None (0)'	System	28 Oct 2020 19:20:10
	System	28 Oct 2020 19:20:10

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-28T14:20:08', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'dc2b4572-48a7-4574-aa8a-e81401f62c9b' User entered '28 Oct 2020 14:20'	System	28 Oct 2020 19:20:10
	System	28 Oct 2020 19:20:10

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	21 Oct 2020 02:38:18
User entered 'Day 8'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-22T20:35:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e7d82176-1c88-4387-9276-8277977b1fc6' User entered 'No (N)'	System	23 Oct 2020 01:36:05
	System	23 Oct 2020 01:36:05

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-22T20:36:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e7d82176-1c88-4387-9276-8277977b1fc6' User entered '22 Oct 2020 20:36'	System	23 Oct 2020 01:36:05
	System	23 Oct 2020 01:36:05

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 02:38:18

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	22 Oct 2020 03:21:17
User entered 'Day 9'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T00:28:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '40c30712-24f3-4107-9661-78f2d24a2945' User entered 'No (N)'	System	24 Oct 2020 05:28:54
	System	24 Oct 2020 05:28:54

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T00:28:52', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '40c30712-24f3-4107-9661-78f2d24a2945' User entered '24 Oct 2020 00:28'	System	24 Oct 2020 05:28:54
	System	24 Oct 2020 05:28:54

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 03:21:17

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	23 Oct 2020 01:35:56
User entered 'Day 10'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T20:27:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2bd523a4-874f-4735-b356-9e5f49c946ef' User entered 'No (N)'	System	25 Oct 2020 01:27:40
	System	25 Oct 2020 01:27:40

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-24T20:27:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2bd523a4-874f-4735-b356-9e5f49c946ef' User entered '24 Oct 2020 20:27'	System	25 Oct 2020 01:27:40
	System	25 Oct 2020 01:27:40

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 01:35:56

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	24 Oct 2020 05:28:45
User entered 'Day 11'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-25T20:16:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fa546a43-1584-44b6-9737-788d761eebfa' User entered 'No (N)'	System	26 Oct 2020 01:16:44
	System	26 Oct 2020 01:16:44

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-25T20:16:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'fa546a43-1584-44b6-9737-788d761eebfa' User entered '25 Oct 2020 20:16'	System	26 Oct 2020 01:16:44
	System	26 Oct 2020 01:16:44

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '25 Oct 2020 12:00'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Oct 2020 11:59'	System	24 Oct 2020 05:28:45

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	25 Oct 2020 01:27:32
User entered 'Day 12'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-26T20:04:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af3605c3-f340-41cf-b219-246e9c1e4345'	System	27 Oct 2020 01:04:40
User entered 'Yes (Y)'	System	27 Oct 2020 01:04:40

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-26T20:04:38', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'af3605c3-f340-41cf-b219-246e9c1e4345'	System	27 Oct 2020 01:04:40
User entered '26 Oct 2020 20:04'	System	27 Oct 2020 01:04:40

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '26 Oct 2020 12:00'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Oct 2020 11:59'	System	25 Oct 2020 01:27:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	26 Oct 2020 01:16:36
User entered 'Day 13'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 01:16:36

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	27 Oct 2020 01:04:32
User entered 'Day 14'	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-28T14:20:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ae83f3d1-d56f-4f84-83e3-dcb20abaf514' User entered 'No (N)'	System	28 Oct 2020 19:20:27
	System	28 Oct 2020 19:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-10-28T14:20:20', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ae83f3d1-d56f-4f84-83e3-dcb20abaf514' User entered '28 Oct 2020 14:20'	System	28 Oct 2020 19:20:27
	System	28 Oct 2020 19:20:27

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 01:04:32

US3342182

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:09:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 01:04:32

US3342182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Oct 2020 17:27:32

US3342182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '22 Oct 2020'	Ethan Shotton (b) (4)	22 Oct 2020 17:27:32

US3342182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	22 Oct 2020 17:27:32

US3342182

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	22 Oct 2020 17:27:32

US3342182

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	22 Oct 2020 17:27:36

US3342182

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	22 Oct 2020 17:27:36

US3342182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Oct 2020 16:55:35

US3342182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '29 Oct 2020'	Ethan Shotton (b) (4)	29 Oct 2020 16:55:35

US3342182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	29 Oct 2020 16:55:35

US3342182

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Ethan Shotton (b) (4)	29 Oct 2020 16:55:35

US3342182

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	29 Oct 2020 16:55:38

US3342182

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	29 Oct 2020 16:55:38

US3342182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:01:03

US3342182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '5 Nov 2020'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:01:03

US3342182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Contact Made (CONTACT MADE)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:01:03

US3342182

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:01:03

US3342182

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:01:09

US3342182

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	05 Nov 2020 16:01:09

US3342182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:47:28

US3342182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:47:28

US3342182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:47:28

US3342182

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'VISIT3'	System	13 Nov 2020 22:47:28

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '15:35'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '13 Nov 2020 15:35'	System	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '65'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'bpm'	System	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'breaths/min'	System	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '136'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '80'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'mmHg'	System	13 Nov 2020 22:48:19

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:27

US3342182

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:27

US3342182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	17 Nov 2020 21:12:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '13 Nov 2020'	Morgan Schulle (b) (4)	17 Nov 2020 21:12:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered '16:34'	Morgan Schulle (b) (4)	17 Nov 2020 21:12:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered '13 Nov 2020 16:34'	System	17 Nov 2020 21:12:00

US3342182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	12 Feb 2021 23:48:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:48:32

US3342182

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	13 Nov 2020 22:48:32

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 64'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-03T15:25:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bd392e4b-fbcd-4e70-825d-6ccea7abf47f' User entered 'No (N)'	System	03 Nov 2020 21:25:53
	System	03 Nov 2020 21:25:53

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-03T15:25:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bd392e4b-fbcd-4e70-825d-6ccea7abf47f' User entered 'No (N)'	System	03 Nov 2020 21:25:53
	System	03 Nov 2020 21:25:53

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-03T15:25:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'bd392e4b-fbcd-4e70-825d-6ccea7abf47f' User entered '03 Nov 2020 15:25:51'	System	03 Nov 2020 21:25:53
	System	03 Nov 2020 21:25:53

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 71'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-10T10:16:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '439ff5da-db36-4de7-a0b7-e99e6d7e2499'	System	10 Nov 2020 16:16:54
User entered 'No (N)'	System	10 Nov 2020 16:16:54

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-10T10:16:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '439ff5da-db36-4de7-a0b7-e99e6d7e2499'	System	10 Nov 2020 16:16:54
User entered 'No (N)'	System	10 Nov 2020 16:16:54

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-10T10:16:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '439ff5da-db36-4de7-a0b7-e99e6d7e2499' User entered '10 Nov 2020 10:16:51'	System	10 Nov 2020 16:16:54
	System	10 Nov 2020 16:16:54

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered 'Day 78'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-19T13:52:15', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '22222e2e-17fc-45af-b111-7c5df346730c'	System	19 Nov 2020 19:52:29
User entered 'No (N)'	System	19 Nov 2020 19:52:29

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-19T13:52:22', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '22222e2e-17fc-45af-b111-7c5df346730c'	System	19 Nov 2020 19:52:29
User entered 'No (N)'	System	19 Nov 2020 19:52:29

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-19T13:52:26', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '22222e2e-17fc-45af-b111-7c5df346730c' User entered '19 Nov 2020 13:52:26'	System	19 Nov 2020 19:52:29
	System	19 Nov 2020 19:52:29

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:50:44

US3342182

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:03:03
Data entry locked.	System	03 Sep 2020 19:50:44
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:50:44

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-24T21:51:11', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2eb61125-288b-40a1-b4c9-743584efcadc' User entered 'No (N)'	System	25 Nov 2020 03:51:23
	System	25 Nov 2020 03:51:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-24T21:51:16', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2eb61125-288b-40a1-b4c9-743584efcad'	System	25 Nov 2020 03:51:23
User entered 'No (N)'	System	25 Nov 2020 03:51:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-24T21:51:19', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2eb61125-288b-40a1-b4c9-743584efcadc' User entered '24 Nov 2020 21:51:19'	System	25 Nov 2020 03:51:23
	System	25 Nov 2020 03:51:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-28T11:23:56', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '57e05daf-281e-4b81-8ff7-e3db798b290f' User entered 'No (N)'	System	28 Nov 2020 17:24:09

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-28T11:24:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '57e05daf-281e-4b81-8ff7-e3db798b290f' User entered 'No (N)'	System	28 Nov 2020 17:24:09

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-11-28T11:24:07', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '57e05daf-281e-4b81-8ff7-e3db798b290f' User entered '28 Nov 2020 11:24:07'	System	28 Nov 2020 17:24:09
	System	28 Nov 2020 17:24:09

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-05T20:56:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b262b6c7-752e-4d4a-ac16-cbb9e63e88ab' User entered 'No (N)'	System	06 Dec 2020 02:56:47
	System	06 Dec 2020 02:56:47

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-05T20:56:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b262b6c7-752e-4d4a-ac16-cbb9e63e88ab' User entered 'No (N)'	System	06 Dec 2020 02:56:47
	System	06 Dec 2020 02:56:47

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-05T20:56:46', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'b262b6c7-752e-4d4a-ac16-cbb9e63e88ab' User entered '05 Dec 2020 20:56:46'	System	06 Dec 2020 02:56:47
	System	06 Dec 2020 02:56:47

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-12T22:29:27', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8b6bc9ae-34fa-4f59-ac5f-75b71a42a5ad' User entered 'No (N)'	System	13 Dec 2020 04:29:39
	System	13 Dec 2020 04:29:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-12T22:29:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8b6bc9ae-34fa-4f59-ac5f-75b71a42a5ad' User entered 'No (N)'	System	13 Dec 2020 04:29:39
	System	13 Dec 2020 04:29:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-12T22:29:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '8b6bc9ae-34fa-4f59-ac5f-75b71a42a5ad' User entered '12 Dec 2020 22:29:36'	System	13 Dec 2020 04:29:39
	System	13 Dec 2020 04:29:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-19T22:15:44', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ef48aa0f-f7b3-4a08-b4d7-dbd0bd301fc6'	System	20 Dec 2020 04:15:54
User entered 'No (N)'	System	20 Dec 2020 04:15:54

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-19T22:15:47', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ef48aa0f-f7b3-4a08-b4d7-dbd0bd301fc6'	System	20 Dec 2020 04:15:54
User entered 'No (N)'	System	20 Dec 2020 04:15:54

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-19T22:15:51', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ef48aa0f-f7b3-4a08-b4d7-dbd0bd301fc6' User entered '19 Dec 2020 22:15:51'	System	20 Dec 2020 04:15:54
	System	20 Dec 2020 04:15:54

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-26T09:45:50', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c9faf3de-8d12-4c36-8d4a-01a60a1d0112'	System	26 Dec 2020 15:46:04
User entered 'No (N)'	System	26 Dec 2020 15:46:04

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-26T09:45:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c9faf3de-8d12-4c36-8d4a-01a60a1d0112'	System	26 Dec 2020 15:46:04
User entered 'No (N)'	System	26 Dec 2020 15:46:04

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2020-12-26T09:46:01', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c9faf3de-8d12-4c36-8d4a-01a60a1d0112' User entered '26 Dec 2020 09:46:01'	System	26 Dec 2020 15:46:04
	System	26 Dec 2020 15:46:04

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-02T00:02:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '60c28732-16d7-406a-8e53-006781811008'	System	02 Jan 2021 06:02:12
User entered 'No (N)'	System	02 Jan 2021 06:02:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-02T00:02:06', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '60c28732-16d7-406a-8e53-006781811008'	System	02 Jan 2021 06:02:12
User entered 'No (N)'	System	02 Jan 2021 06:02:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-02T00:02:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '60c28732-16d7-406a-8e53-006781811008' User entered '02 Jan 2021 00:02:09'	System	02 Jan 2021 06:02:12
	System	02 Jan 2021 06:02:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'Yes (Y)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'Yes (Y)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:23', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'No (N)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:32', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'Yes (Y)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889'	System	09 Jan 2021 18:37:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-09T12:37:40', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '38ecdbef-65e5-4ccf-8b01-ccca9409b889' User entered '09 Jan 2021 12:37:40'	System	09 Jan 2021 18:37:49
	System	09 Jan 2021 18:37:49

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-20T16:58:29', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'd5a5cb61-3817-4846-b8df-914029a455a7' User entered 'No (N)'	System	20 Jan 2021 22:59:15
	System	20 Jan 2021 22:59:15

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-20T16:58:37', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'd5a5cb61-3817-4846-b8df-914029a455a7'	System	20 Jan 2021 22:59:15
User entered 'No (N)'	System	20 Jan 2021 22:59:15

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-20T16:59:12', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'd5a5cb61-3817-4846-b8df-914029a455a7' User entered '20 Jan 2021 16:59:12'	System	20 Jan 2021 22:59:15
	System	20 Jan 2021 22:59:15

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:57:28', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered 'Yes (Y)'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:57:35', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9'	System	24 Jan 2021 03:00:28
User entered 'No (N)'	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:58:41', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered 'Yes (Y)'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '1'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '1'	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '1'	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:03', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '0'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:58:53', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9'	System	24 Jan 2021 03:00:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:59:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered 'Yes (Y)'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T20:59:05', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9'	System	24 Jan 2021 03:00:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-01-23T21:00:18', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2e84a6b4-0c13-49e3-bf76-e8b71ecca9e9' User entered '23 Jan 2021 21:00:18'	System	24 Jan 2021 03:00:28
	System	24 Jan 2021 03:00:28

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-03T16:45:58', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '21925144-376f-4682-bd94-e602b231fb32' User entered 'No (N)'	System	03 Feb 2021 22:46:11
	System	03 Feb 2021 22:46:11

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-03T16:46:04', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '21925144-376f-4682-bd94-e602b231fb32'	System	03 Feb 2021 22:46:11
User entered 'No (N)'	System	03 Feb 2021 22:46:11

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-03T16:46:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '21925144-376f-4682-bd94-e602b231fb32' User entered '03 Feb 2021 16:46:09'	System	03 Feb 2021 22:46:11
	System	03 Feb 2021 22:46:11

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-09T20:28:34', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e8459752-6a93-4280-9607-0dc22f16ea8b' User entered 'No (N)'	System	10 Feb 2021 02:32:12
	System	10 Feb 2021 02:32:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-09T20:28:39', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e8459752-6a93-4280-9607-0dc22f16ea8b' User entered 'No (N)'	System	10 Feb 2021 02:32:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-09T20:28:43', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'e8459752-6a93-4280-9607-0dc22f16ea8b' User entered '09 Feb 2021 20:28:43'	System	10 Feb 2021 02:32:12
	System	10 Feb 2021 02:32:12

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-13T12:46:31', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '04c78c18-4fda-4930-8ef7-fd89de4beff6' User entered 'No (N)'	System	13 Feb 2021 18:46:39
	System	13 Feb 2021 18:46:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-13T12:46:33', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '04c78c18-4fda-4930-8ef7-fd89de4beff6' User entered 'No (N)'	System	13 Feb 2021 18:46:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-13T12:46:36', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '04c78c18-4fda-4930-8ef7-fd89de4beff6'	System	13 Feb 2021 18:46:39
User entered '13 Feb 2021 12:46:36'	System	13 Feb 2021 18:46:39

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-20T22:00:09', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ee8f81d5-812f-45b5-a52a-79ce26b63aaa' User entered 'No (N)'	System	21 Feb 2021 04:00:21
	System	21 Feb 2021 04:00:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-20T22:00:14', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ee8f81d5-812f-45b5-a52a-79ce26b63aaa' User entered 'No (N)'	System	21 Feb 2021 04:00:21
	System	21 Feb 2021 04:00:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-20T22:00:18', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ee8f81d5-812f-45b5-a52a-79ce26b63aaa' User entered '20 Feb 2021 22:00:18'	System	21 Feb 2021 04:00:21
	System	21 Feb 2021 04:00:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-27T11:25:48-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ce2fe705-0d7d-4b78-a061-9783862c4875'	System	05 Mar 2021 00:31:32
User entered 'No (N)'	System	05 Mar 2021 00:31:32

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-27T11:25:50-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ce2fe705-0d7d-4b78-a061-9783862c4875'	System	05 Mar 2021 00:31:32
User entered 'No (N)'	System	05 Mar 2021 00:31:32

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-02-27T11:25:54-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ce2fe705-0d7d-4b78-a061-9783862c4875'	System	05 Mar 2021 00:31:32
User entered '27 Feb 2021 17:25:54'	System	05 Mar 2021 00:31:32

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-06T23:09:57-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2bc11501-7c37-4eb6-bf3e-7c8933275487'	System	07 Mar 2021 05:10:14
User entered 'No (N)'	System	07 Mar 2021 05:10:14

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-06T23:10:04-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2bc11501-7c37-4eb6-bf3e-7c8933275487'	System	07 Mar 2021 05:10:14
User entered 'No (N)'	System	07 Mar 2021 05:10:14

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-06T23:10:09-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '2bc11501-7c37-4eb6-bf3e-7c8933275487' User entered '06 Mar 2021 23:10:09'	System	07 Mar 2021 05:10:14
	System	07 Mar 2021 05:10:14

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-13T10:09:13-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ff18dbba-5e8d-4ab1-a754-c4f1636f2ccf'	System	13 Mar 2021 16:09:21
User entered 'No (N)'	System	13 Mar 2021 16:09:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-13T10:09:15-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ff18dbba-5e8d-4ab1-a754-c4f1636f2ccf' User entered 'No (N)'	System	13 Mar 2021 16:09:21
	System	13 Mar 2021 16:09:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-13T10:09:19-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'ff18dbba-5e8d-4ab1-a754-c4f1636f2ccf'	System	13 Mar 2021 16:09:21
User entered '13 Mar 2021 10:09:19'	System	13 Mar 2021 16:09:21

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-22T16:10:50-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c75356fb-fcda-4b89-a4a2-a4436305d2a6'	System	22 Mar 2021 21:10:59
User entered 'No (N)'	System	22 Mar 2021 21:10:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-22T16:10:53-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c75356fb-fcda-4b89-a4a2-a4436305d2a6'	System	22 Mar 2021 21:10:59
User entered 'No (N)'	System	22 Mar 2021 21:10:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-22T16:10:57-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'c75356fb-fcda-4b89-a4a2-a4436305d2a6'	System	22 Mar 2021 21:10:59
User entered '22 Mar 2021 16:10:57'	System	22 Mar 2021 21:10:59

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-27T11:18:20-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6686e867-e85a-43ef-802e-0b484ad0ffe7'	System	27 Mar 2021 16:18:57
User entered 'No (N)'	System	27 Mar 2021 16:18:57

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-27T11:18:25-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6686e867-e85a-43ef-802e-0b484ad0ffe7'	System	27 Mar 2021 16:18:57
User entered 'No (N)'	System	27 Mar 2021 16:18:57

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-27T11:18:28-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6686e867-e85a-43ef-802e-0b484ad0ffe7' User entered '27 Mar 2021 11:18:28'	System	27 Mar 2021 16:18:57
	System	27 Mar 2021 16:18:57

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-05T12:40:45-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7bab84c7-87cb-469a-afaf-61db64909678'	System	05 Apr 2021 17:41:06
User entered 'No (N)'	System	05 Apr 2021 17:41:06

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-05T12:40:49-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7bab84c7-87cb-469a-afaf-61db64909678'	System	05 Apr 2021 17:41:06
User entered 'No (N)'	System	05 Apr 2021 17:41:06

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-05T12:40:59-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '7bab84c7-87cb-469a-afaf-61db64909678' User entered '05 Apr 2021 12:40:59'	System	05 Apr 2021 17:41:06
	System	05 Apr 2021 17:41:06

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-10T22:43:10-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6a195a35-241c-4399-a66f-f073a62d65ab' User entered 'No (N)'	System	11 Apr 2021 03:43:19
	System	11 Apr 2021 03:43:19

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-10T22:43:07-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6a195a35-241c-4399-a66f-f073a62d65ab' User entered 'No (N)'	System	11 Apr 2021 03:43:19
	System	11 Apr 2021 03:43:19

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-10T22:43:15-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '6a195a35-241c-4399-a66f-f073a62d65ab'	System	11 Apr 2021 03:43:19
User entered '10 Apr 2021 22:43:15'	System	11 Apr 2021 03:43:19

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-19T16:10:44-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'be9e986b-9c50-4578-a1b2-13a6255a796f' User entered 'No (N)'	System	19 Apr 2021 21:10:58
	System	19 Apr 2021 21:10:58

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-19T16:10:50-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'be9e986b-9c50-4578-a1b2-13a6255a796f' User entered 'No (N)'	System	19 Apr 2021 21:10:58
	System	19 Apr 2021 21:10:58

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-19T16:10:54-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'be9e986b-9c50-4578-a1b2-13a6255a796f' User entered '19 Apr 2021 16:10:54'	System	19 Apr 2021 21:10:58
	System	19 Apr 2021 21:10:58

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-24T20:01:27-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1504321-a32c-437d-be89-287553b41712'	System	25 Apr 2021 01:06:23
User entered 'No (N)'	System	25 Apr 2021 01:06:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-24T20:01:32-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1504321-a32c-437d-be89-287553b41712'	System	25 Apr 2021 01:06:23
User entered 'No (N)'	System	25 Apr 2021 01:06:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-04-24T20:01:36-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: 'a1504321-a32c-437d-be89-287553b41712'	System	25 Apr 2021 01:06:23
User entered '24 Apr 2021 20:01:36'	System	25 Apr 2021 01:06:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-05-03T20:50:41-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '85e3f08d-9d45-4579-91c3-53542a03b9a4'	System	04 May 2021 01:50:51
User entered 'No (N)'	System	04 May 2021 01:50:51

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

Have you been exposed to someone with 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 (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-05-03T20:50:45-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '85e3f08d-9d45-4579-91c3-53542a03b9a4'	System	04 May 2021 01:50:51
User entered 'No (N)'	System	04 May 2021 01:50:51

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-05-03T20:50:49-05:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '85e3f08d-9d45-4579-91c3-53542a03b9a4'	System	04 May 2021 01:50:51
User entered '03 May 2021 20:50:49'	System	04 May 2021 01:50:51

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:31:23

US3342182

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:31:23
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:31:23

US3342182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:09:07

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 02:06:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-04T18:31:47-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '77d6d74f-14b1-41f1-8c08-2cd74b768486'	System	05 Mar 2021 00:31:57
User entered 'No (N)'	System	05 Mar 2021 00:31:57

US3342182

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:09:07

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:06:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4C59CFBF-474F-4AC4-80FC-854F942880B8)', Time: '2021-03-04T18:31:54-06:00', User OID: 'PatientReportedOutcome (US3342182)', ODM File OID: '77d6d74f-14b1-41f1-8c08-2cd74b768486' User entered '04 Mar 2021 18:31:54'	System	05 Mar 2021 00:31:57
	System	05 Mar 2021 00:31:57

US3342182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Dec 2020 16:27:18

US3342182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '8 Dec 2020'	Ethan Shotton (b) (4)	08 Dec 2020 16:27:18

US3342182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4)	08 Dec 2020 16:27:18

US3342182

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Ethan Shotton (b) (4)	08 Dec 2020 16:27:18

US3342182

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	08 Dec 2020 16:27:23

US3342182

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:51:00
User entered 'I'	System	08 Dec 2020 16:27:23

US3342182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
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).	(b) (4)	28 Jan 2021 15:11:53
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	28 Jan 2021 15:11:17
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 15:11:17

US3342182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:11:17

US3342182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty; reason for change Data Entry Error	(b) (4)	28 Jan 2021 15:11:53
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Jan 2021 15:11:17

US3342182

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'patient was COVID (+) was being monitored via daily phone calls'	(b) (4), (b) (6)	28 Jan 2021 15:11:17

US3342182

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:00

US3342182

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User entered 'I'	System	28 Jan 2021 15:12:00

US3342182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:11

US3342182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:47:16
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'can confirm out of window, note to file to be created for these protocol deviations' (Site from System).	Olivia Hapanowicz (b) (4) (b) (4)	28 Jan 2021 17:52:37
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Jan 2021 15:12:11
User entered '28 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 15:12:11

US3342182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:11

US3342182

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4), (b) (6)	28 Jan 2021 15:12:11

US3342182

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:12:14

US3342182

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User entered 'I'	System	28 Jan 2021 15:12:14

US3342182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:05

US3342182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 13:35:27
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'site was closed due to Severe Weather' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 21:42:23
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Feb 2021 21:42:05
User entered '25 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 21:42:05

US3342182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:05

US3342182

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:05

US3342182

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:28

US3342182

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:31:13
User entered '1'	System	25 Feb 2021 21:42:28

US3342182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:50:06
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '01 Apr 2021'	Morgan Schulle (b) (4)	01 Apr 2021 18:50:06
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	01 Apr 2021 18:50:06
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 18:50:06

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '01 Apr 2021'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '13:17'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 13:17'	System	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '98.6' F	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Oral (Oral)'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '84'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '14'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '142'	(b) (4) Morgan Schulle (b) (4)	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '79'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:02
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:51:02

US3342182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'No (N)'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:13
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:51:13
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	06 Apr 2021 15:06:53
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '01 Apr 2021'	Ethan Shotton (b) (4)	06 Apr 2021 15:06:53
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '13:49'	Ethan Shotton (b) (4)	06 Apr 2021 15:06:53
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 13:49'	System	06 Apr 2021 15:06:53

US3342182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:51:31
	(b) (4)	

US3342182

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:51:31

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 23-DEC-2020 is reported under illness visit day 1 in PPD portal; however, swab sample for 23-DEC-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 04:40:47
Query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 23-DEC-2020 is reported under illness visit day 1 in PPD portal; however, swab sample for 23-DEC-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider updating swab data in the COVID Diagnostic Test eCRF, else clarify.' answered with 'this is in EDC' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:43:10
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:48:44
User opened query 'Per GCL Lab Reconciliation requery: Swab: Sample dated 23-DEC-2020 is reported under illness visit day 1 in PPD portal; however, swab sample for 23-DEC-2020 is missing in EDC. Kindly confirm if swab sample was collected if yes, consider updating swab data in the COVID Diagnostic Test eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:06:50
User closed query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:06:50
Query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' answered with 'UPDATING FORM' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:12:30

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 23DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 22:44:50
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:10:46
User closed query 'Please provide time in source. Prev discussion with CRC, CRC stated time documented is appt time but it is not listed in source.' (Site from CRA).	(b) (4), (b) (6)	05 Mar 2021 17:10:09
Query 'Please provide time in source. Prev discussion with CRC, CRC stated time documented is appt time but it is not listed in source. ' answered with 'Source updated.' (Site from CRA).	Ethan Shotton (b) (4) (b) (4)	05 Mar 2021 14:43:47
User opened query 'Please provide time in source. Prev discussion with CRC, CRC stated time documented is appt time but it is not listed in source.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:51:04
User entered '13:00'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:12
User entered '23 Dec 2020 13:00'	System	24 Dec 2020 01:12:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:48:57
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:48:59
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 1 (Day 1)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:43:18
User entered '19 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User closed query 'Source does not show assessment on D1. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:10:34
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source does not show assessment on D1. Please review and reconcile. ' answered with 'illness day 1 symptoms recorded on illness visit day 1 source ' (Site from CRA).	Morgan Schulle (b) (4)	03 Mar 2021 22:11:56
User opened query 'Source does not show assessment on D1. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:45:27
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:45:10
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:44:48
User entered '0'	Darrell O'Brien (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:50
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:44:52
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Moderate (Moderate)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:12:55

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 2 (Day 2)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:49:45
User entered '20 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User closed query 'Source does not show assessment on D2. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:10:51
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source does not show assessment on D2. Please review and reconcile. ' answered with 'Source provides that Sx were ongoing for this date. Sx log for this date collected at Illness Visit. Pulse OX and Temp not assessed, but Sx were garnered through patient interview.' (Site from CRA).	Darrell O'Brien (b) (4)	05 Mar 2021 13:53:34
User opened query 'Source does not show assessment on D2. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:50:13
User entered '0'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:49:47
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:49:48
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Moderate (Moderate)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 3 (Day 3)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:28
User entered '21 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User closed query 'Source does not show symptoms on D3. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:11:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source does not show symptoms on D3. Please review and reconcile. ' answered with 'Source provides that Sx were ongoing for this date. Sx log for this date collected at Illness Visit. Pulse OX and Temp not assessed, but Sx were garnered through patient interview.' (Site from CRA).	Darrell O'Brien (b) (4)	05 Mar 2021 13:53:38
User opened query 'Source does not show symptoms on D3. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:51:00
User entered '0'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:29
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:50:35
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Moderate (Moderate)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 4 (Day 4)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:28
User entered '22 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User closed query 'Source does not show symptoms on D4. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:11:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source does not show symptoms on D4. Please review and reconcile. ' answered with 'Source provides that Sx were ongoing for this date. Sx log for this date collected at Illness Visit. Pulse OX and Temp not assessed, but Sx were garnered through patient interview.' (Site from CRA).	Darrell O'Brien (b) (4)	05 Mar 2021 13:53:50
User opened query 'Source does not show symptoms on D4. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:51:53
User entered '0'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:30
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:51:33
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Moderate (Moderate)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:12:24
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'None (None)'	(b) (4) Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:13:50

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 5 (Day 5)'	Darrell O'Brien (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:52:35
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:52:38
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:52:49
User entered '100'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:52:51
User entered '99' F	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:52:59
User entered 'Moderate (Moderate)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:53:03
User entered 'Moderate (Moderate)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:24
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:14:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 6 (Day 6)'	Darrell O'Brien (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:54:07
User entered '24 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:54:03
User entered '99'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:54:05
User entered '97.7' F	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:54:16
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:54:22
User entered 'Mild (Mild)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:22
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	25 Dec 2020 14:47:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 7 (Day 7)'	Darrell O'Brien (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered '25 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:55:01
User entered '98'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:55:03
User entered '98.4' F	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:08:20
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:34:53

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 8 (Day 8)'	Darrell O'Brien (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:09
User entered '26 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:07
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:04
User entered '99'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:05
User entered '98.2' F	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:25
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:27
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:29
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:30
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:32
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:34
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:35
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:37
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:39
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:41
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:42
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:44
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:45
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:48
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:49
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:02:51
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	27 Dec 2020 00:35:34

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 9 (Day 9)'	Darrell O'Brien (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:21
User entered '27 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:23
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:30
User entered '98'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:31
User entered '97.5' F	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:33
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:34
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:36
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:38
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:40
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:43
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:45
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:47
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:49
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:51
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:52
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:54
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:55
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:57
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:04:59
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:05:00
User entered 'None (None)'	Darrell O'Brien (b) (4) (b) (4)	28 Dec 2020 14:52:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 10 (Day 10)'	(b) (4) Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered '28 Dec 2020'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered '0'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered '98'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered '97.7' F	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:09:57
User entered 'None (None)'	Stefanie Mott (b) (4)	28 Dec 2020 21:35:54

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 11 (Day 11)'	(b) (4) Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered '29 Dec 2020'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered '0'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered '98'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered '97.7' F	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:01
User entered 'None (None)'	Stefanie Mott (b) (4)	29 Dec 2020 22:05:57

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 12 (Day 12)'	(b) (4) Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered '30 Dec 2020'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered '0'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered '98'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered '97.7' F	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:03
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:30:32

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 13 (Day 13)'	(b) (4) Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered '31 Dec 2020'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered '0'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered '99'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered '97.9' F	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:05
User entered 'None (None)'	Stefanie Mott (b) (4)	01 Jan 2021 00:34:40

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 14 (Day 14)'	(b) (4) Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered '1 Jan 2021'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered '0'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered '98'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered '97.1' F	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:06
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 01:42:22

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 15 (Day 15)'	(b) (4) Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered '2 Jan 2021'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered '0'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered '99'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	02 Jan 2021 23:49:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered '97.9' F	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:08
User entered 'None (None)'	Stefanie Mott (b) (4)	02 Jan 2021 23:49:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 16 (Day 16)'	(b) (4) Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered '3 Jan 2021'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered '98'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered '97.9' F	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:11
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 00:04:19

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 17 (Day 17)'	(b) (4) Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered '4 Jan 2021'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered '98'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered '97.5' F	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:12
User entered 'None (None)'	Stefanie Mott (b) (4)	04 Jan 2021 23:19:38

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 18 (Day 18)'	(b) (4) Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered '5 Jan 2021'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered '0'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered '96'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered '97.9' F	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:51:32
User closed query 'Source states moderate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 17:51:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source states moderate. Please review and reconcile.' answered with 'Updated' (Site from CRA).	(b) (4)	05 Mar 2021 13:59:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	05 Mar 2021 13:59:36
DataPoint Un-verified.	(b) (4)	03 Feb 2021 21:10:24
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 21:10:14
User opened query 'Source states moderate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 21:09:04
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:10:14
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 01:03:12

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 19 (Day 19)'	(b) (4) Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered '6 Jan 2021'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered '0'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered '96'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered '100.9' F reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:33:51
User entered '97.9' F	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:33:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:33:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:51
User entered 'None (None)'	Stefanie Mott (b) (4)	06 Jan 2021 23:31:56

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 20 (Day 20)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered '7 Jan 2021'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered '0'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered '95'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered '99.8' F	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:56
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 15:21:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 21 (Day 21)'	(b) (4) Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered '8 Jan 2021'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered '0'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered '98'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered '99.5' F	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:57
User entered 'None (None)'	Stefanie Mott (b) (4)	08 Jan 2021 22:49:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 22 (Day 22)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered '9 Jan 2021'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered '0'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered '96'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered '99.6' F	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:19:59
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 00:31:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 23 (Day 23)'	(b) (4) Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered '10 Jan 2021'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered '0'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered '95'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered '101.3' F	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	11 Jan 2021 01:31:40
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:00
User entered 'None (None)'	Stefanie Mott (b) (4)	11 Jan 2021 01:28:30

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 24 (Day 24)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered '11 Jan 2021'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered '0'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered '95'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered '101' F	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:02
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 14:21:29

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 25 (Day 25)'	(b) (4) Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered '12 Jan 2021'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered '0'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered '95'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered '100.6' F	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:20:03
User entered 'None (None)'	Stefanie Mott (b) (4)	12 Jan 2021 17:24:08

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 28 (Day 28)'	(b) (4) Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered '15 Jan 2021'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered '0'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered '95'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	15 Jan 2021 21:38:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered '100.7' F	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Severe (Severe)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:47
User entered 'None (None)'	Stefanie Mott (b) (4)	15 Jan 2021 21:38:17

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 29 (Day 29)'	(b) (4) Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered '16 Jan 2021'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered '0'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered '93'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered '99.7' F reason for change: Data Entry Error	Stefanie Mott (b) (4)	18 Jan 2021 17:11:19
User entered empty.	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:49
User entered 'None (None)'	Stefanie Mott (b) (4)	17 Jan 2021 23:14:11

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 30 (Day 30)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered '17 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered '94'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered '98.1' F	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:50
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 17:12:15

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Day 31 (Day 31)'	(b) (4) Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered '18 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered '95'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User entered '%'	System	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered '98.2' F	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'Mild (Mild)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'Moderate (Moderate)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:09:07

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:21
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:35:51
User entered 'None (None)'	Stefanie Mott (b) (4)	18 Jan 2021 23:35:10

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:15:02
DataPoint Un-verified.	Stefanie Mott (b) (4)	05 Apr 2021 15:43:11
Signature has been broken.	Stefanie Mott (b) (4)	05 Apr 2021 15:43:11
User entered '12 Jan 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	05 Apr 2021 15:43:11
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:39
User entered '23 Dec 2020'	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:41
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:37:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:15:02
User closed query 'Per eCRF guidelines pg. 54, "If the results for SARs-CoV-2 NP swab are NEGATIVE and then followed up with a POSITIVE Saliva test, add a new (duplicate) COVID-19 Assessment Folder by adding via ADD EVENT Drop down and enter the following forms only: ? COVID-19 Contact Form (original contact details) ? COVID Diagnostic Test – with details and results of the negative NP Swab ? All other forms in that folder can be deactivated by DM or your CRA"' (Site from CRA). Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:14:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
User signature succeeded.	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
Query 'Per eCRF guidelines pg. 54, "If the results for SARs-CoV-2 NP swab are NEGATIVE and then followed up with a POSITIVE Saliva test, add a new (duplicate) COVID-19 Assessment Folder by adding via ADD EVENT Drop down and enter the following forms only: ? COVID-19 Contact Form (original contact details) ? COVID Diagnostic Test – with details and results of the negative NP Swab ? All other forms in that folder can be deactivated by DM or your CRA"' answered with 'will add diagnostic test with saliva information' (Site from CRA). User entered 'No (N)' reason for change: Data Entry Error	Paul Pickrell (b) (4) (b) (4) Eileen Euperio (b) (4) (b) (4)	13 Mar 2021 15:22:08 09 Feb 2021 16:36:44 09 Feb 2021 16:36:23

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
User opened query 'Per eCRF guidelines pg. 54, "If the results for SARs-CoV-2 NP swab are NEGATIVE and then followed up with a POSITIVE Saliva test, add a new (duplicate) COVID-19 Assessment Folder by adding via ADD EVENT Drop down and enter the following forms only: ? COVID-19 Contact Form (original contact details) ? COVID Diagnostic Test – with details and results of the negative NP Swab ? All other forms in that folder can be deactivated by DM or your CRA"' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:07:51
User closed query 'Please complete COVID-19 Severity Assessment page as expected.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:52:20
Query 'Please complete COVID-19 Severity Assessment page as expected.' answered with 'UPDATED, PLEASE ALSO NOTE THAT THE NP LAB ON 23DEC2020 WAS NEGATIVE BUT SALIVA ON 12JAN21 WAS +' (Site from CRA).	Eileen Euperio (b) (4)	01 Feb 2021 20:13:54
User opened query 'Please complete COVID-19 Severity Assessment page as expected.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 22:52:27
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)	18 Jan 2021 07:48:21
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 'confirmed with day 21 saliva' (Site from System).	Stefanie Mott (b) (4)	15 Jan 2021 21:40:11
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	15 Jan 2021 21:39:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	15 Jan 2021 21:39:59
User entered 'No (N)'	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:37:06
User closed query 'Source states 23DEC2020. Please review and reconcile. ' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:15:24
	(b) (4), (b) (6)	08 Apr 2021 18:15:02
Signature has been broken.	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
	(b) (4)	
User entered '23 Dec 2020' reason for change: Data Entry Error	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source states 23DEC2020. Please review and reconcile. ' answered with '23Dec2020 was the NP swab which was negative, site got positive result from D21 saliva' (Site from CRA).	(b) (4)	
User opened query 'Source states 23DEC2020. Please review and reconcile. ' (Site from CRA).	Eileen Euperio (b) (4)	09 Feb 2021 16:36:23
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Eileen Euperio (b) (4)	09 Feb 2021 16:35:07
	(b) (4)	
User entered '23 Dec 2020'	(b) (4), (b) (6)	02 Feb 2021 17:08:41
	(b) (4)	
	Stefanie Mott (b) (4)	15 Jan 2021 21:39:59
	(b) (4)	
	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45
	(b) (4)	

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:37:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 04:45:00
User closed query 'Source states NP. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:15:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:15:02
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'updated date' (Site from DM).	Stefanie Mott (b) (4)	05 Apr 2021 15:42:59
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12JAN2021 is recorded under Covid-19 Assessment in EDC, however the same is reported under COVID PCR Saliva Day 21 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:00:27
Signature has been broken.	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	24 Mar 2021 19:49:56
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	09 Feb 2021 16:36:23
Query 'Source states NP. Please review and reconcile. ' answered with '23Dec2020 was the NP swab which was negative, site got positive result from D21 saliva' (Site from CRA).	Eileen Euperio (b) (4)	09 Feb 2021 16:35:10

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Type of Test Performed

Audit	User	Time (GMT)
User opened query 'Source states NP. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:08:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:08:43
User entered 'Saliva Test (Saliva Test)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	15 Jan 2021 21:39:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:03
User entered empty.	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[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)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:05
User entered 'No (N)'	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:08
User entered empty.	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:09
User entered empty.	Stefanie Mott (b) (4)	12 Jan 2021 17:26:45

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:27
User entered '1'	System	24 Mar 2021 19:49:56
User entered '0'	System	09 Feb 2021 16:36:23
User entered '1'	System	15 Jan 2021 21:39:59
User entered '0'	System	12 Jan 2021 17:26:45

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User closed query 'Source does not include severity assessment. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:14:37
Query 'Source does not include severity assessment. Please clarify. ' answered with 'symptom severity source filed ' (Site from CRA).	Stefanie Mott (b) (4)	24 Mar 2021 19:45:54
User opened query 'Source does not include severity assessment. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:40:05
User closed query 'Please provide severity assessment source for review' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:40:05
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Please provide severity assessment source for review' answered with 'source is present in subject folder' (Site from CRA).	Eileen Euperio (b) (4)	09 Feb 2021 16:42:36
User opened query 'Please provide severity assessment source for review' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 20:47:17
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

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Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

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)	30 Apr 2021 18:16:31
User signature succeeded.	Paul Pickrell (b) (4)	28 Apr 2021 16:37:27
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 04:00:54
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 29 (16Jan21), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:29:44
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 29 (16Jan21), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'Updated.' (Site from DM).	Ethan Shotton (b) (4)	21 Apr 2021 13:48:57
DataPoint Un-verified.	Ethan Shotton (b) (4)	21 Apr 2021 13:48:18
Signature has been broken.	Ethan Shotton (b) (4)	21 Apr 2021 13:48:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	21 Apr 2021 13:48:18
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 29 (16Jan21), Kindly note "Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:07:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:13:18

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
Signature has been broken.	(b) (4) Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
Signature has been broken.	(b) (4) Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User entered '17 Jan 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
Signature has been broken.	(b) (4) Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
Signature has been broken.	(b) (4)	
	Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User entered '17 Jan 2021' reason for change: Data Entry Error	Stefanie Mott (b) (4)	24 Mar 2021 19:45:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18
	(b) (4)	

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:09:07

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	01 Feb 2021 20:13:18

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:09:07

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:36
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	01 Feb 2021 20:13:26

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:46
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:51:53
Signature has been broken.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:51:53
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 18:51:53
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:24:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '12 Jan 2021'	(b) (4)	
	Eileen Euperio (b) (4)	09 Feb 2021 16:40:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:49
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:54:25
Signature has been broken.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:54:25
User entered '13:00' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 18:54:25
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:24:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '00:00'	Eileen Euperio (b) (4)	09 Feb 2021 16:40:24
	(b) (4)	

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:41
User entered '23 Dec 2020 13:00'	System	24 Mar 2021 18:54:25
User entered '23 Dec 2020 00:00'	System	24 Mar 2021 18:51:53
User entered '12 Jan 2021 00:00'	System	09 Feb 2021 16:40:24

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:46:48
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:54:11
Signature has been broken.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:54:11
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:54:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:24:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Eileen Euperio (b) (4)	09 Feb 2021 16:40:24
	(b) (4)	

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:07

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:16:41
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:24:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Feb 2021 16:40:24

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
Signature has been broken.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 18:56:06
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '12 Jan 2021'	(b) (4)	
	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43
	(b) (4)	

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
Signature has been broken.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
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) (4), (b) (6)	10 Feb 2021 14:26:53
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 'this AE is already in EDC. saliva sample was +' (Site from System).	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:41:06
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	09 Feb 2021 16:40:43
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:40:43

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
Signature has been broken.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
User entered '23 Dec 2020' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:41:00
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'Subject tested positive outside of site and Saliva sample also came out positive after a negative swab result. Subject was entered into the same convalescent phase. PD noted.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	05 Mar 2021 14:07:28
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:42:56
User entered '12 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	09 Feb 2021 16:40:43

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:14:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
Signature has been broken.	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	(b) (4) Ethan Shotton (b) (4)	24 Mar 2021 18:56:06
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Saliva Test (Saliva Test)'	(b) (4) Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[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)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:25:03
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Eileen Euperio (b) (4)	09 Feb 2021 16:40:43

US3342182

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:09:07

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:17:11
User entered '0'	System	24 Mar 2021 18:56:06
User entered '1'	System	09 Feb 2021 16:40:43

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '25 Dec 2020'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '27 Dec 2020'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '29 Dec 2020'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '31 Dec 2020'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '5 Jan 2021'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '12 Jan 2021'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:09:07

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:09:07

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	20 Jan 2021 19:50:16
User entered 'NA (COVID-19 Negative) (NA)'	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:37:05
User entered '19 Jan 2021' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	20 Jan 2021 19:50:16
User entered empty.	Stefanie Mott (b) (4)	12 Jan 2021 17:28:20

US3342182

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:23
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:23
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,27,29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	02 Feb 2021 08:05:56
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,27,29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:16:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25,27,29DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	07 Jan 2021 06:40:26
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:23
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered 'SICKD1'	System	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '13:20'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered '23 Dec 2020 13:20'	System	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	24 Dec 2020 01:11:32
DataPoint set to visible.	(b) (4) System	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	24 Dec 2020 01:11:32
DataPoint set to visible.	(b) (4) System	24 Dec 2020 01:11:02

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '99' F	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered 'Oral (Oral)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '69'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered 'bpm'	System	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '12'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered 'breaths/min'	System	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '131'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered 'mmHg'	System	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered '91'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User entered 'mmHg'	System	24 Dec 2020 01:11:32

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27

US3342182

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27

US3342182

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:25
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:40

US3342182

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:25
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:40

US3342182

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:09:07

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:29
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:47

US3342182

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:09:07

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:29
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:47:28
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'REQ 1F602888207 HAS SAMPLES REGISTERED' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:15:04
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 06:46:46
User entered '23 Dec 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Dec 2020 01:11:47

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:30:37
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:30:37
User entered '19 Jan 2021'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:30:37
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered 'SICKD28'	System	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '19 Jan 2021'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '10:22'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered '19 Jan 2021 10:22'	System	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	19 Jan 2021 17:27:45
DataPoint set to visible.	(b) (4) System	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered missing code ND - Not Done.	Darrell O'Brien (b) (4)	19 Jan 2021 17:27:45
DataPoint set to visible.	(b) (4) System	19 Jan 2021 17:26:55

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '98.6' F	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered 'Oral (Oral)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '80'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered 'bpm'	System	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '14'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered 'breaths/min'	System	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User entered '105'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered 'mmHg'	System	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:38
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	20 Jan 2021 13:26:25
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:55
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		19 Jan 2021 17:27:45
User entered '59'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User entered 'mmHg'	System	19 Jan 2021 17:27:45

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:55
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:34:41

US3342182

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:31:55
User entered '19 Jan 2021'	Darrell O'Brien (b) (4) (b) (4)	19 Jan 2021 17:34:41

US3342182

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:09:07

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:32:08
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	20 Jan 2021 19:50:25

US3342182

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:09:07

Date of Collection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:25:13
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 10:20:22
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:32:08
Query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' answered with 'REQ 1F603116186 ACCESSIONED IN PPD' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:16:29
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 19 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 11:12:54
User entered '19 Jan 2021'	Eileen Euperio (b) (4) (b) (4)	20 Jan 2021 19:50:25

US3342182

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	John Luna (b) (4)	02 Feb 2021 21:40:51

US3342182

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '2 Feb 2021'	John Luna (b) (4)	02 Feb 2021 21:40:51

US3342182

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Clinic (Clinic)'	John Luna (b) (4)	02 Feb 2021 21:40:51

US3342182

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'UNBLND_DECIDE'	System	02 Feb 2021 21:40:51

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '2 Feb 2021'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	Ethan Shotton (b) (4)	09 Mar 2021 13:35:41
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:33:10

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ethan Shotton (b) (4)	09 Mar 2021 13:35:41
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:33:10

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '2 Feb 2021'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Placebo (Placebo)'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Placebo (Placebo)'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Placebo (Placebo)'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	John Luna (b) (4)	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '1'	System	02 Feb 2021 21:41:16

US3342182

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:07

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'I'	System	02 Feb 2021 21:41:16

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered empty.	System	03 Mar 2021 23:20:43
DataPoint set to visible.	System	02 Feb 2021 21:41:16

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered empty.	System	03 Mar 2021 23:20:43
DataPoint set to visible.	System	02 Feb 2021 21:41:16

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '13:36'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '03 Mar 2021 13:36'	System	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '80'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'bpm'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '16'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'breaths/min'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '146'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'mmHg'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '89'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'mmHg'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered empty.	System	03 Mar 2021 23:20:43
DataPoint set to visible.	System	02 Feb 2021 21:41:16

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '16:58'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '03 Mar 2021 16:58'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '80'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'bpm'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '14'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'breaths/min'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '134'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'mmHg'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '78'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'mmHg'	System	03 Mar 2021 23:20:43

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:49

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:49

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'mRNA-1273'	System	03 Mar 2021 23:21:17
DataPoint set to visible.	System	02 Feb 2021 21:41:16

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '16:28'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '03 Mar 2021 16:28'	System	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'ONCE'	System	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 23:21:17

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:24

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Mar 2021'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:24

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '16:03'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:24

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '03 Mar 2021 16:03'	System	09 Mar 2021 21:35:24

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:36

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Mar 2021'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:36

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '16:04'	Ethan Shotton (b) (4)	09 Mar 2021 21:35:36

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:07

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered '03 Mar 2021 16:04'	System	09 Mar 2021 21:35:36

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 23:20:53

US3342182

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:07:27
User entered 'I'	System	03 Mar 2021 23:20:53

US3342182

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 16:42:18

US3342182

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '10 Mar 2021'	(b) (4), (b) (6)	10 Mar 2021 16:42:18

US3342182

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Mar 2021 16:42:18

US3342182

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 16:42:18

US3342182

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 16:42:29

US3342182

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User entered '1'	System	10 Mar 2021 16:42:29

US3342182

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:55:17
User entered '1'	System	10 Mar 2021 16:42:29
DataPoint set to visible.	System	10 Mar 2021 16:42:29

US3342182

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:19
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '01 Apr 2021'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:19
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Clinic (Clinic)'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:19
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:07

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	01 Apr 2021 18:52:19

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '01 Apr 2021'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '13:17'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 13:17'	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '98.6' F	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'Oral (Oral)'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '84'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '14'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '142'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered '79'	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:49:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 19:49:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 19:49:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 18:52:58
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '14:43' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 14:43'	System	01 Apr 2021 19:49:03
User entered empty.	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '98.5' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:52:58
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '81' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	01 Apr 2021 19:49:03
User entered empty.	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	01 Apr 2021 19:49:03
User entered empty.	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '131' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 19:49:03
User entered empty.	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '72' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:49:03
User entered empty.	Morgan Schulle (b) (4) (b) (4)	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:07

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	01 Apr 2021 19:49:03
User entered empty.	System	01 Apr 2021 18:52:58

US3342182

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered 'No (N)'	Morgan Schulle (b) (4)	01 Apr 2021 18:53:06
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:07

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
	(b) (4)	
User entered empty.	Morgan Schulle (b) (4)	01 Apr 2021 18:53:06
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	01 Apr 2021 19:48:21
DataPoint set to visible.	System	10 Mar 2021 16:42:29

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '01 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '14:13'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 14:13'	System	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:07

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	01 Apr 2021 19:48:21

US3342182

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:37:06
	(b) (4)	
User entered 'Yes (Y)'	Morgan Schulle (b) (4)	01 Apr 2021 18:53:12
	(b) (4)	

US3342182

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 18:53:12

US3342182

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:29:03

US3342182

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:29:03

US3342182

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:29:03

US3342182

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:07

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:29:03

US3342182

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Apr 2021 15:50:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:29:13

US3342182

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:07

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 14:29:13

US3342182

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:09:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:44:31
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 131 (09JAN2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:49:19
Query 'Per DM CLR: Per Safety Follow Up Diary Day 131 (09JAN2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Subject recorded "Yes" on diary due to their symptoms felt during their convalescent period. AE for COVID-19 Infection already recorded.' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 18:43:57
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 131 (09JAN2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 07:28:55
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:39:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 21:20:05

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:41:11
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Per investigator, the medication induced headache is not a worsening of the patient's ongoing med history condition, it is a new diagnosis.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	16 Nov 2020 21:10:25
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:34:40
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Drug-induced headache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:19:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 23:19:43
Data point term sent to Coder	System	15 Oct 2020 22:26:46
User entered 'Medication induced headache'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:49
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:13:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:53
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 03SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:11:35
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 03SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'The headaches starting on 03SEP2020 in eDiary were reported as a separate AE.' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:14:02
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 03SEP2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:34:28
User entered '18 Sep 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:46:01
User entered '10 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:57
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User entered empty.	System	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 19:46:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '28 Oct 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 19:46:01
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:03
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User entered empty.	System	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:05
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:07
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:11
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:14
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:16
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:27
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:29
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:31
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:33
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:36
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:38
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:46:01
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 22:27:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 22:27:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 22:27:05
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 22:26:10
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:06:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Patient was wrongly prescribed 20 mg of lexapro in lieu of the normally prescribed 20 mg of citalopram starting on 18 SEP 2020. Patient has stated they are experiencing exacerbated headaches following the first vaccination bit attributes the continuation of this symptom to the change in medication.'	(b) (4), (b) (6)	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User entered '0'	System	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07
User entered 'I'	System	15 Oct 2020 22:26:10

US3342182

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:07

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:24
Data point term sent to Coder	System	28 Oct 2020 19:48:18
User entered 'Generalized Anxiety'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:47
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:51
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:53
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '26 Oct 2020'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:55
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:57
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:59
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:03
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:05
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:08
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:10
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:14
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:16
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:17
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:23
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:25
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:27
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:29
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:31
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'None (NONE)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:33
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:35
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'l'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:37
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:38
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:40
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:05:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 19:47:29

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 13:26:00
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'No, this is not a worsening it is just a headache of normal severity after the vaccine' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	19 Jan 2021 22:21:21
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:06:40
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 05:39:38

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'No Illness visit scheduled. Will log PD for missed unscheduled covid illness visit.' (Site from DM).	Darrell O'Brien (b) (4)	24 Dec 2020 01:09:59
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 15:52:44
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:04:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:04:53
Data point term sent to Coder	System	17 Nov 2020 14:13:14
User entered 'Headache post-vaccination'	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:22
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:24
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:26
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '03 Sep 2020'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:28
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '15:07'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User entered '03 Sep 2020 15:07'	System	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:50
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '17 Sep 2020'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '10:00'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User entered '17 Sep 2020 10:00'	System	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:54
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:56
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:03:58
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:00
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:04
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:08
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:11
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:17
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Related (RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:22
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'None (NONE)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:24
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'I'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:26
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:27
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:29
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:32
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:04:33
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User entered '0'	System	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14
User entered '0'	System	17 Nov 2020 14:12:31

US3342182

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:50:14

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:51
User entered	System	19 Jan 2021 20:56:46
'USA-US203-2021-mRNA-1273-P301000005'		
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 20:56:46

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' canceled (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:28:52
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:28:45
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) (b) (4)	15 Jan 2021 21:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 21:41:59
Data point term sent to Coder	System	15 Jan 2021 21:41:04
Coding entries removed.	Stefanie Mott (b) (4)	15 Jan 2021 21:40:42
User entered 'COVID-19 INFECTION' reason for change: Data Entry Error	Stefanie Mott (b) (4)	15 Jan 2021 21:40:42
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 14:00:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 14:00:43
Data point term sent to Coder	System	04 Jan 2021 23:31:56
User entered 'viral URI AE'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	15 Jan 2021 21:40:42
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '19 Dec 2020'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:49:24
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:05:16
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'END DATE RECORDED' (Site from DM).	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:16:00
DataPoint Un-verified.	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:15:48
User entered 'No (N)' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:15:48
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:48:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:52:56
User entered '05 Feb 2021' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:20:07
DataPoint Un-verified.	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:15:48
User entered '25 Jan 2021' reason for change: Data Entry Error	Morgan Schulle (b) (4) (b) (4)	03 Mar 2021 22:15:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 17:02:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:45:53
User entered empty.	System	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 21:44:45
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
User closed query 'Source states Yes. Please review and reconcile. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 05:37:31
Query 'Source states Yes. Please review and reconcile. ' answered with 'Event does not qualify as SAE. correction made on source' (Site from CRA).	Darrell O'Brien (b) (4) (b) (4)	10 Feb 2021 22:53:34
User opened query 'Source states Yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:59:20
Query 'Source states Yes. ' canceled (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:59:07
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:04
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User opened query 'Source states Yes. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:57:33
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered 'Not Applicable (NOT APPLICABLE)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User closed query 'Per CDM: Other Action Taken = ConMed. However, there is no corresponding ConMed record that is indicated for this AE. Please reconcile with ConMed eCRF page and update indication of the medications given as treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:31:05
Query 'Per CDM: Other Action Taken = ConMed. However, there is no corresponding ConMed record that is indicated for this AE. Please reconcile with ConMed eCRF page and update indication of the medications given as treatment for this AE as appropriate. Otherwise, clarify.' answered with 'CONMEDS ARE IN LOG' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:17:51
User opened query 'Per CDM: Other Action Taken = ConMed. However, there is no corresponding ConMed record that is indicated for this AE. Please reconcile with ConMed eCRF page and update indication of the medications given as treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:33:51
User entered 'I'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 17:52:49
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 14:01:06
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'ENTERED RESOLVED DATE' (Site from Safety).	Morgan Schulle (b) (4)	03 Mar 2021 22:16:14
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:15:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	03 Mar 2021 22:15:48
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 17:45:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:59:00
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:31:07

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:04:20
User closed query 'Source does not indicate a positive test on 06JAN2021. Source states a test was taken on 23DEC2020 and no results as of 23DEC2020. Please review and clarify. Source also states subject reported fever, chills, SOB, fatigue, body aches, new loss of taste, nausea, vomiting, and diarrhea when subject re-entered convalescent period. Please review and confirm symptoms and date of outside test results since source does not reflect date..' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 18:04:16
User closed query 'PV Query: Please complete symptom logs from 19Jan2021 until date of resolution. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:59:48
User closed query 'PV Query: Please confirm type of testing performed on 06 Jan 2021 outside of study. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:59:46
User closed query 'PV Query: It was reported that site received NP swab results and were negative. Please provide date of that test. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:59:43
User closed query 'PV Query: Please confirm actual date for Day 28 saliva test with negative result. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:59:34
User closed query 'PV Query: Please confirm actual date of saliva test from Day 21 with positive result. Day 21 on symptom log is 08 Jan 2021 but recent query response said positive saliva test was 19 Jan 2021. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:59:20
Query 'PV Query: Please complete symptom logs from 19Jan2021 until date of resolution. ' answered with 'Subject tested negative for COVID-19 at D28 Illness Visit. Symptom Log not necessary as subject did not have to restart convalescent period.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 21:51:15
Query 'PV Query: Please confirm type of testing performed on 06 Jan 2021 outside of study. If unknown, please indicate so. ' answered with 'Unknown.' (Site from Safety).	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 20:06:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: It was reported that site received NP swab results and were negative. Please provide date of that test. ' answered with 'Date of test: 23Dec2021 - Negative result reported 12Jan2021. Both dates included in source.' (Site from Safety).	Ethan Shotton (b) (4)	24 Mar 2021 20:03:04
Query 'PV Query: Please confirm actual date for Day 28 saliva test with negative result. ' answered with 'Actual date of Day 28 Saliva Test: 19Jan2021 (per lab source for Illness Visit D28) - Result negative on 26Jan2021' (Site from Safety).	Ethan Shotton (b) (4)	24 Mar 2021 20:01:44
Query 'PV Query: Please confirm actual date of saliva test from Day 21 with positive result. Day 21 on symptom log is 08 Jan 2021 but recent query response said positive saliva test was 19 Jan 2021. Please clarify. ' answered with 'Date of saliva test is 12Jan2021 per source (21st day of convalescent period is 25 log line in symptom log). Positive result came on 15Jan2021 from Day 21 saliva sample.' (Site from Safety).	Ethan Shotton (b) (4)	24 Mar 2021 20:00:02
Query 'Source does not indicate a positive test on 06JAN2021. Source states a test was taken on 23DEC2020 and no results as of 23DEC2020. Please review and clarify. Source also states subject reported fever, chills, SOB, fatigue, body aches, new loss of taste, nausea, vomiting, and diarrhea when subject re-entered convalescent period. Please review and confirm symptoms and date of outside test results since source does not reflect date..' answered with 'Convalescent Telemedicine Visit Day 15 source states subject tested positive outside of site on 06Jan2021 in notes section.' (Site from CRA).	Ethan Shotton (b) (4)	24 Mar 2021 19:16:13
User opened query 'PV Query: Please complete symptom logs from 19Jan2021 until date of resolution. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:49:21
User opened query 'PV Query: Please confirm type of testing performed on 06 Jan 2021 outside of study. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:49:11
User opened query 'PV Query: It was reported that site received NP swab results and were negative. Please provide date of that test. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:49:02

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm actual date for Day 28 saliva test with negative result. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:48:38
User opened query 'PV Query: Please confirm actual date of saliva test from Day 21 with positive result. Day 21 on symptom log is 08 Jan 2021 but recent query response said positive saliva test was 19 Jan 2021. Please clarify. ' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:48:17
User opened query 'Source does not indicate a positive test on 06JAN2021. Source states a test was taken on 23DEC2020 and no results as of 23DEC2020. Please review and clarify. Source also states subject reported fever, chills, SOB, fatigue, body aches, new loss of taste, nausea, vomiting, and diarrhea when subject re-entered convalescent period. Please review and confirm symptoms and date of outside test results since source does not reflect date..' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:56:36
User closed query 'Please provide narrative in source to verify ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 21:56:36
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	12 Mar 2021 23:37:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME ONSITE ON 23DEC2021 WITH SYMPTOMS OF MODERATE HEADACHE AND DIARRHEA. SUBJECT TESTED + OUTSIDE ON STUDY 06JAN21. SITE RECEIVED NP SWAB RESULTS AND WERE NEGATIVE FROM DAY-ADVISED BY SPONSOR THAT SUBJECT COULD EXIT CONVALESCENT PERIOD 12JAN2021. SITE LATER RECEIVED REPORT FROM SALIVA TEST DAY 21 + RESULT AND SUBJECT RE-ENTERD CONVALESCENT PERIOD. SUBJECT THEN REPORTED FEVER, CHILLS, SOB, FATIGUE, AND BODY ACHES.SUBJECT FOLLOWED UP WITH PCP AND WAS GIVEN PREDNISONE, ALBUTEROL, ONDASTERONM AND AZITHROMYCIN FOR SYMPTOMS. SUBJECT RETURNED TO SITE 19JAN21 WITH SYMPTOMS ONGOING COUGH, SOB, FATIGUE, BODY ACHES, HEADACHE. RESULT FROM D28 SALIVA NEGATIVE. LAST COVID SYMPTOMS RESOLVED ON 05FEB2021' reason for change: Data Entry Error	Morgan Schulle (b) (4)	03 Mar 2021 22:20:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME ONSITE ON 23DEC2021 WITH SYMPTOMS OF MODERATE HEADACHE AND DIARRHEA. SUBJECT TESTED + OUTSIDE ON STUDY 06JAN21. SITE RECEIVED NP SWAB RESULTS AND WERE NEGATIVE FROM DAY-ADVISED BY SPONSOR THAT SUBJECT COULD EXIT CONVALESCENT PERIOD 12JAN2021. SITE LATER RECEIVED REPORT FROM SALIVA TEST DAY 21 + RESULT AND SUBJECT RE-ENTERD CONVALESCENT PERIOD. SUBJECT THEN REPORTED FEVER, CHILLS, SOB, FATIGUE, AND BODY ACHES.SUBJECT FOLLOWED UP WITH PCP AND WAS GIVEN PREDNISONE, ALBUTEROL, ONDASTERONM AND AZITHROMYCIN FOR SYMPTOMS. SUBJECT RETURNED TO SITE 19JAN21 WITH SYMPTOMS ONGOING COUGH, SOB, FATIGUE, BODY ACHES, HEADACHE. RESULT FROM D28 SALIVA NEGATIVE. LAST COVID SYMPTOMS RESOLVED ON 05JAN2021' reason for change: Data Entry Error	Morgan Schulle (b) (4)	03 Mar 2021 22:20:07
Query 'Please provide narrative in source to verify ' answered with 'NARRATIVE PROVIDED' (Site from CRA).	Morgan Schulle (b) (4)	03 Mar 2021 22:16:21

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME ONSITE ON 23DEC2021 WITH SYMPTOMS OF MODERATE HEADACHE AND DIARRHEA. SUBJECT TESTED + OUTSIDE ON STUDY 06JAN21. SITE RECEIVED NP SWAB RESULTS AND WERE NEGATIVE FROM DAY-ADVISED BY SPONSOR THAT SUBJECT COULD EXIT CONVALESCENT PERIOD 12JAN2021. SITE LATER RECEIVED REPORT FROM SALIVA TEST DAY 21 + RESULT AND SUBJECT RE-ENTERD CONVALESCENT PERIOD. SUBJECT THEN REPORTED FEVER, CHILLS, SOB, FATIGUE, AND BODY ACHES.SUBJECT FOLLOWED UP WITH PCP AND WAS GIVEN PREDNISONE, ALBUTEROL, ONDASTERONM AND AZITHROMYCIN FOR SYMPTOMS. SUBJECT RETURNED TO SITE 19JAN21 WITH SYMPTOMS ONGOING COUGH, SOB, FATIGUE, BODY ACHES, HEADACHE. RESULT FROM D28 SALIVA NEGATIVE. LAST COVID SYMPTOMS RESOLVED ON 25JAN2021' reason for change: Data Entry Error	Morgan Schulle (b) (4)	03 Mar 2021 22:15:48
User closed query 'PV Query: Please provide completed Covid-19 severity assessment form.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 00:03:42
User closed query 'PV Query: Please confirm date of SARS-CoV-2 RT-PCR test.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 00:03:39
User opened query 'Please provide narrative in source to verify ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:01:47
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:24
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:59:00

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CAME ONSITE ON 23DEC2021 WITH SYMPTOMS OF MODERATE HEADACHE AND DIARRHEA. SUBJECT TESTED + OUTSIDE ON STUDY 06JAN21. SITE RECEIVED NP SWAB RESULTS AND WERE NEGATIVE FROM DAY-ADVISED BY SPONSOR THAT SUBJECT COULD EXIT CONVALESCENT PERIOD 12JAN2021. SITE LATER RECEIVED REPORT FROM SALIVA TEST DAY 21 + RESULT AND SUBJECT RE-ENTERD CONVALESCENT PERIOD. SUBJECT THEN REPORTED FEVER, CHILLS, SOB, FATIGUE, AND BODY ACHES.SUBJECT FOLLOWED UP WITH PCP AND WAS GIVEN PREDNISONE, ALBUTEROL, ONDASTERONM AND AZITHROMYCIN FOR SYMPTOMS. SUBJECT RETURNED TO SITE 19JAN21 WITH SYMPTOMS ONGOING COUGH, SOB, FATIGUE, BODY ACHES, HEADACHE. RESULT FROM D28 SALIVA NEGATIVE' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:28:16
Query 'PV Query: Please confirm date of SARS-CoV-2 RT-PCR test.' answered with 'POSITIVE SALVIA TEST WAS ON 19JAN2021. THE PREVIOUS COVID SAMPLES WERE NEGATIVE' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:20:28
Query 'PV Query: Please provide completed Covid-19 severity assessment form.' answered with 'THIS IS UP TO DATE' (Site from Safety).	Eileen Euperio (b) (4) (b) (4)	01 Feb 2021 20:20:03
User opened query 'PV Query: Please provide completed Covid-19 severity assessment form.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	26 Jan 2021 17:45:35
User opened query 'PV Query: Please confirm date of SARS-CoV-2 RT-PCR test.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	26 Jan 2021 17:45:28
User entered empty.	Stefanie Mott (b) (4) (b) (4)	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:09:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Jan 2021 23:31:07

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:50:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 19:02:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 19:02:39
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:47:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 18:47:39
Data point term sent to Coder	System	24 Mar 2021 18:46:16
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Olivia Hapanowicz (b) (4) (b) (4)	24 Mar 2021 18:45:44
Coding entries removed.	Olivia Hapanowicz (b) (4) (b) (4)	24 Mar 2021 18:45:37
Signature has been broken.	Olivia Hapanowicz (b) (4) (b) (4)	24 Mar 2021 18:45:37
User entered 'worsening TENSION HEADACHES' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4) (b) (4)	24 Mar 2021 18:45:37
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:21:32

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 20:08:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 20:08:03
	(b) (4)	
Data point term sent to Coder	System	04 Mar 2021 20:07:16
User entered 'tension headaches'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '05 Feb 2021'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:03:21
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE ongoing as of 01Apr2021.' (Site from DM).	Olivia Hapanowicz (b) (4)	05 Apr 2021 14:59:06
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:10:35
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
User entered 'Yes (Y)'	(b) (4) Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '1'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	12 Mar 2021 23:37:28
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 20:07:12

US3342182

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:09:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 20:07:12

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:09:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:44:31
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:54
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:51:33

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 19:53:49
Data point term sent to Coder	System	03 Sep 2020 19:52:44
User entered 'allegra'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'seasonal allergies'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '60'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2019'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:52:37

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:54:52
Data point term sent to Coder	System	03 Sep 2020 19:53:46
User entered 'citalopram'	Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'depression'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '20'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'mg (mg)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4)	03 Sep 2020 19:53:30
	Stefanie Mott (b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'once daily (QD)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Oral (ORAL)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'un UNK 2010'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 20:02:40
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	03 Sep 2020 19:53:30
	Stefanie Mott (b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered '13 Oct 2020' reason for change: Data Entry Error	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:15:29
User entered empty.	(b) (4)	
	Ethan Shotton (b) (4)	28 Oct 2020 20:02:40
	(b) (4)	
	Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Stefanie Mott (b) (4)	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User entered '1'	System	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User entered '1'	System	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:12
User entered '804 (804)'	System	03 Sep 2020 19:53:30

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 19:57:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:57:45
Data point term sent to Coder	System	03 Sep 2020 19:55:51
User entered 'triamterene/hydrochlorothiazide'	Stefanie Mott (b) (4) (b) (4) (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'hypertension'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '37.5/25'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2019'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:54:51

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:56:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:56:43
Data point term sent to Coder	System	03 Sep 2020 19:55:54
User entered 'amlodipine'	Stefanie Mott (b) (4) (b) (4) (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'hypertension'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '2.5'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2019'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:55:25

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:57:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:57:46
Data point term sent to Coder	System	03 Sep 2020 19:56:55
User entered 'montelukast'	Stefanie Mott (b) (4) (b) (4) (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'seasonal allergies'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '10'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:55:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 06:18:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:18:31
Data point term sent to Coder	System	03 Sep 2020 19:57:57
User entered 'guifenesin'	Stefanie Mott (b) (4) (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'seasonal allergies'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '1200'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:57:05

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Sep 2020 19:59:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 19:59:41
Data point term sent to Coder	System	03 Sep 2020 19:58:58
User entered 'tylenol'	Stefanie Mott (b) (4) (b) (4) (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'headaches'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '650'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2000'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 19:57:59

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Sep 2020 22:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 22:11:45
Data point term sent to Coder Coding entries removed.	System John Luna (b) (4)	09 Sep 2020 22:10:36 09 Sep 2020 22:10:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:04:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:04:44
Data point term sent to Coder User entered 'vitamin d'	System Stefanie Mott (b) (4) (b) (4)	03 Sep 2020 19:59:59 03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'vitamin d deficiency'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '2000'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'IU (IU)'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 22:10:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 22:10:26
User entered 'Oral (ORAL)' reason for change: Data John Luna Entry Error	(b) (4)	09 Sep 2020 22:10:26
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 19:59:14
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'un UNK 2010'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 19:59:14

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:01:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:01:46
Data point term sent to Coder	System	03 Sep 2020 20:01:01
User entered 'synthroid'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'hypothyroidism'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of dose ranges. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:18:42
Query 'Per DM CLR: Please provide the actual dose for this medication instead of dose ranges. Update the Dose and Dose Unit fields as appropriate.' answered with 'pt takes 88 mcg monday-friday' (Site from DM).	Stefanie Mott (b) (4)	06 Jan 2021 23:15:34
User entered '88' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:15:28
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of dose ranges. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:11:15
User entered '44-88'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'ug (ug)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'other (OTHER)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '5 times/week'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '01 Jun 2020'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:00:11

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:59:33
Data point term sent to Coder	System	28 Oct 2020 19:50:25
User entered 'Ibuprofen'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 19:49:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Headaches'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '400'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'as needed (PRN)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'UN UNK 2000'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 19:49:58
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:49:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:49:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 19:49:58

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per DM CLR: this Con Med was added on 18 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 14:54:00
Query 'Per DM CLR: this Con Med was added on 18 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'pt wrongly prescribed escitalopram instead of usual citalopram. this was an error made by pt's primary care and was not due to an AE' (Site from DM).	Stefanie Mott (b) (4)	06 Jan 2021 23:20:03
User opened query 'Per DM CLR: this Con Med was added on 18 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:07:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:01:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:01:36
Data point term sent to Coder	System	28 Oct 2020 20:01:42
User entered 'Escitalopram'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Depression'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '20'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'mg (mg)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'once daily (QD)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Oral (ORAL)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '18 Sep 2020'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '15 Oct 2020'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User entered '1'	System	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User entered '1'	System	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:08
User entered '804 (804)'	System	28 Oct 2020 20:01:19

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 20:07:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:07:24
Data point term sent to Coder	System	28 Oct 2020 20:07:58
Data point term sent to Coder	System	28 Oct 2020 20:06:52
User entered 'Alprazolam'	Ethan Shotton (b) (4) (b) (4)	28 Oct 2020 20:06:01

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'Generalized Anxiety AE' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered '0.5' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'mg (mg)' reason for change: Data Entry Error	System	28 Oct 2020 20:07:12
User opened query 'Data is required. Please complete.' (Site from System).	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
User entered empty.	(b) (4)	
	System	28 Oct 2020 20:06:01
	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'other (OTHER)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'QHS' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System (b) (4)	28 Oct 2020 20:07:12
User entered '26 Oct 2020' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System (b) (4)	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:07:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:07:12
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	28 Oct 2020 20:07:12
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 20:06:01
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:06:01
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:06:01

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:06:01

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 20:06:01

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 22:16:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:09:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 03:09:10
Data point term sent to Coder	System	28 Oct 2020 20:08:59
User entered 'Cortisone Injection'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Headache AE'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'UNK'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Other (OTHER)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'UNK'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'once (ONCE)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Other (OTHER)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Cervical epidural space'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '21 Oct 2020'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '21 Oct 2020'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Ethan Shotton (b) (4)	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:55:40
User entered empty.	System	28 Oct 2020 20:08:13

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
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)	05 Nov 2020 16:41:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:41:24
Data point term sent to Coder	System	05 Nov 2020 16:17:42
User entered 'High dose influenza vaccination.'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Influenza prophylaxis'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0.5'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'mL (mL)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'once (ONCE)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:21:58
User entered '3 Nov 2020'	(b) (4)	
	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:21:58
User entered '3 Nov 2020'	(b) (4)	
	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	System	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	System	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:17
User entered empty.	System	05 Nov 2020 16:17:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Nov 2020 14:18:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:18:47
Data point term sent to Coder	System	17 Nov 2020 14:18:30
User entered 'Citalopram'	Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Depression'	(b) (4) Olivia Hapanowicz (b) (4) (b) (4)	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '20'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'once daily (QD)'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Oral (ORAL)'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '14 Oct 2020'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered '0'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'Yes (Y)'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered empty.	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User entered 'No (N)'	(b) (4) Olivia Hapanowicz (b) (4)	17 Nov 2020 14:17:39
	(b) (4)	

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 14:17:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:22:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:22:28
Data point term sent to Coder	System	18 Jan 2021 21:21:02
Coding entries removed.	Stefanie Mott (b) (4)	18 Jan 2021 21:20:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 23:31:35
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 Jan 2021 23:31:35
Data point term sent to Coder	System	04 Jan 2021 23:30:56
User entered 'ibuprofen'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:53
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:57
User entered 'covid-19 infection AE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	18 Jan 2021 21:20:43
User entered 'viral URI AE'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:59
User entered '400'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:20:10
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:20:12
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:47:47
User closed query 'Source states daily and prn. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:47:45
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.	(b) (4), (b) (6)	04 Mar 2021 14:04:50
' (Site from DM).		
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.	Morgan Schulle (b) (4)	03 Mar 2021 22:29:34
' answered with 'updated to prn on edc and source' (Site from DM).	(b) (4)	
Query 'Source states daily and prn. Please review and reconcile.' answered with 'updated to prn on edc and source' (Site from CRA).	Morgan Schulle (b) (4)	03 Mar 2021 22:29:25
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.	(b) (4), (b) (6)	10 Feb 2021 05:35:23
' (Site from DM).		
User opened query 'Source states daily and prn. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:20:42
User entered 'once (ONCE)'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:20:57
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:21:02
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 23:30:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 23:30:07
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	04 Jan 2021 23:30:07
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 23:30:02
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:21:03
User entered empty.	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:21:07
User entered '4 Jan 2021'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:21:08
User entered '0'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:48:34
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:29:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 22:29:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:21:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:16:03
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:48:32
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:29:13
User entered '11 Jan 2021' reason for change: New Information	(b) (4)	03 Mar 2021 22:29:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:21:17
User entered empty; reason for change New Information	Stefanie Mott (b) (4)	06 Jan 2021 23:16:03
User entered '4 Jan 2021'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:48:31
User closed query 'Source states Yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:48:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source states Yes. Please review and reconcile. ' answered with 'source says yes for taken for AE. this was not taken for solicited AR' (Site from CRA).	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:29:52
User opened query 'Source states Yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:21:59
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User entered empty.	System	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User entered empty.	System	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:23
User entered empty.	System	04 Jan 2021 23:30:02

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
Data point term sent to Coder	System	18 Jan 2021 21:21:01
Coding entries removed.	Stefanie Mott (b) (4)	18 Jan 2021 21:20:29
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:46:32
Data point term sent to Coder	System	06 Jan 2021 23:17:51
User entered 'albuterol'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'No (N)'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'covid-19 infection AE' reason for change: Data Entry Error	Stefanie Mott (b) (4)	18 Jan 2021 21:20:29
User entered 'viral URI AE'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered '90'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'ug (ug)'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered '06 Jan 2021'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered '0'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:49:10
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:50:10
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Updated' (Site from DM).	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 21:55:05
DataPoint Un-verified.	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 21:55:02
Signature has been broken.	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 21:55:02
User entered 'No (N)' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	24 Mar 2021 21:55:02
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 06:21:19
User signature succeeded.	Paul Pickrell (b) (4) (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:49:14
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:07
DataPoint Un-verified.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 21:55:02
Signature has been broken.	(b) (4)	
	Ethan Shotton (b) (4)	24 Mar 2021 21:55:02
User entered '05 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:27:37
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:49:20
User closed query 'Source states yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:49:18
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Query 'Source states yes. Please review and reconcile. ' answered with 'source updated to say yes for taken for an AE. this was not taken for solicited AR' (Site from CRA).	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:28:17
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:27:45
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:27:37
User opened query 'Source states yes. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:27:26
User entered 'No (N)'	Stefanie Mott (b) (4)	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User entered empty.	System	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User entered empty.	System	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:29
User entered empty.	System	06 Jan 2021 23:17:26

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Jan 2021 23:19:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 23:19:31
Data point term sent to Coder	System	06 Jan 2021 23:18:52
User entered 'synthroid'	Stefanie Mott (b) (4) (b) (4) (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'hypothyroidism'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '44'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'ug (ug)'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'other (OTHER)'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '2 times/week'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 23:18:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 23:18:16
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Stefanie Mott (b) (4)	06 Jan 2021 23:18:16
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 23:18:10
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '01 Jun 2020'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Jan 2021 23:18:10

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
Data point term sent to Coder	System	18 Jan 2021 21:22:02
User entered 'prednisone'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'covid-19 infection AE'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered '40'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'mg (mg)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered '16 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered '17 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:31:22
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered '1'	System	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered '1'	System	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:36
User entered '804 (804)'	System	18 Jan 2021 21:21:23

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:33:09
Data point term sent to Coder	System	18 Jan 2021 21:22:02
User entered 'prednisone'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'covid-19 infection AE'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered '20'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'mg (mg)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered '18 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:49:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:23:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 22:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:49:54
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:23:12
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:23:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:32:00
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '1'	System	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '1'	System	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:41
User entered '804 (804)'	System	18 Jan 2021 21:21:56

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:47:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:47:10
Data point term sent to Coder	System	18 Jan 2021 21:23:03
User entered 'ONDASTERON'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'COVID-19 INFECTION'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered '4'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'mg (mg)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'as needed (PRN)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered '16 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:50:01
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:24:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 22:24:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:50:04
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:24:42
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4) Morgan Schulle (b) (4)	03 Mar 2021 22:24:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:32
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered empty.	System	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered empty.	System	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:46
User entered empty.	System	18 Jan 2021 21:22:39

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 11:40:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 11:40:04
Data point term sent to Coder	System	18 Jan 2021 23:37:30
User entered 'azithromycin'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'covid-19 infection AE'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered '250'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'mg (mg)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered '17 Jan 2021'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered '0'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:50:14
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:23:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 22:23:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:50:16
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Un-verified.	(b) (4)	
	Morgan Schulle (b) (4)	03 Mar 2021 22:23:34
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 22:23:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered empty.	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:33:33
User entered 'No (N)'	Stefanie Mott (b) (4)	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User entered '1'	System	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User entered '1'	System	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:56:53
User entered '804 (804)'	System	18 Jan 2021 23:36:36

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:28:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:28:19
Data point term sent to Coder	System	04 Mar 2021 20:09:20
User entered 'meloxicam'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'tension headaches AE'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '7.5'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '05 Feb 2021'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:08:48

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: CYCLOBENZAPRINE HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Mar 2021 20:11:09
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 Mar 2021 20:11:09
Data point term sent to Coder	System	04 Mar 2021 20:10:22
User entered 'cyclobenzaprine hcl'	Stefanie Mott (b) (4) (b) (4) (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'tension headaches AE'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '5'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'mg (mg)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'once daily (QD)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Oral (ORAL)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '05 Feb 2021'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered '0'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'Yes (Y)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered empty.	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Stefanie Mott (b) (4)	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:09:07

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 20:09:32

US3342182

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:09:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
	(b) (4)	
User entered 'No (N)'	Ethan Shotton (b) (4)	04 Mar 2021 23:08:07
	(b) (4)	

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'USA-US203-2021-MRNA-1273-P301000005'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Paul'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Pickrell'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'US'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 21:00:25
User entered '3'	System	04 Mar 2021 14:01:38
User entered '2'	System	10 Feb 2021 00:13:52
User entered '1'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'USA-US203-2021-MRNA-1273-P301000005'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Paul'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Pickrell'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'US'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 21:00:25
User entered '3'	System	04 Mar 2021 14:01:38
User entered '2'	System	10 Feb 2021 00:13:52
User entered '1'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered '19/Jan/2021 15:57'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:07

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.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'USA-US203-2021-MRNA-1273-P301000005'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Paul'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Pickrell'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'US'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 21:00:25
User entered '3'	System	04 Mar 2021 14:01:38
User entered '2'	System	10 Feb 2021 00:13:52
User entered '1'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered '09/Feb/2021 18:13'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'USA-US203-2021-MRNA-1273-P301000005'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Paul'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Pickrell'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'US'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 21:00:25
User entered '3'	System	04 Mar 2021 14:01:38
User entered '2'	System	10 Feb 2021 00:13:52
User entered '1'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered '04/Mar/2021 09:01'	System	04 Mar 2021 14:01:38

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 14:01:38

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'USA-US203-2021-MRNA-1273-P301000005'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:37:03
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:56:58
User entered 'No (N)'	System	19 Jan 2021 20:56:46

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Paul'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 21:01:15
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 17:48:57
User entered 'Pickrell'	System	10 Feb 2021 00:13:52

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

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Generated On: 09 Jun 2021 17:09:07

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Pickrell (b) (4)	13 Mar 2021 15:22:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 00:12:46
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:37:03
User entered 'US'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	25 Mar 2021 21:00:25
User entered '3'	System	04 Mar 2021 14:01:38
User entered '2'	System	10 Feb 2021 00:13:52
User entered '1'	System	19 Jan 2021 20:57:06

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:07

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:04:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:09
User entered '25/Mar/2021 17:00'	(b) (4) System	25 Mar 2021 21:00:25

US3342182

Folder: SAE USA-US203-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:07

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:04:59
User signature succeeded.	Paul Pickrell (b) (4)	29 Mar 2021 15:07:09
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 21:01:15
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 21:00:25