

US3412022 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:27:21

All time stamps listed in this document are displayed in GMT

US3412022

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 15:06:55

Generated On: 09 Jun 2021 17:27:21

[Participant ID](#)

US3412022

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

US3412022

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:21:52

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:21:52

Generated On: 09 Jun 2021 17:27:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	HYPERTENSION
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 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	ANXIETY
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 (5)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

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 (6)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	ALLERGIC RHINITIS - SEASONAL;
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 (12)

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Condition	CONTINUOUS POSITIVE AIRWAY PRESSURE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3412022

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:21:52

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	14:39 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 14:39
Height (<i>xxx.x</i>)	185.7 cm
Weight (<i>xxx.x</i>)	169.4 kg
BMI (<i>xxx.x</i>)	49.12353 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:21:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 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: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:52

Generated On: 09 Jun 2021 17:27:21

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:52

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 142277

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	14:39 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 14:39
Temperature (xxx.x)	36.5 C
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)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	16:02 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 16:02
Temperature (xxx.x)	98.4 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 JUL 2020

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 15:30

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	14:57 (24 HR)
Collection date and time (derived)	29 JUL 2020 14:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:52	29 JUL 2020 14:52
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 16:10

PC Open Date & Time

29 JUL 2020 15:50

PC Close Date & Time

29 JUL 2020 18:20

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

96.7 °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	30 JUL 2020 01:30
PC Open Date & Time	29 JUL 2020 19:15
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 21:14

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 17:12

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

02 AUG 2020 00:12

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 12:08

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

03 AUG 2020 12:39

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

04 AUG 2020 17:57

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

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

29 JUL 2020 16:11

PC Open Date & Time

29 JUL 2020 15:50

PC Close Date & Time

29 JUL 2020 18:20

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 01:31

PC Open Date & Time

29 JUL 2020 19:15

PC Close Date & Time

30 JUL 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 21:15

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 17:12

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 00:12

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 12:06

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:38

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 17:57

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 16:12
PC Open Date & Time	29 JUL 2020 15:50
PC Close Date & Time	29 JUL 2020 18:20

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 01:31
PC Open Date & Time	29 JUL 2020 19:15
PC Close Date & Time	30 JUL 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 21:15
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 17:13
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 3570

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 3570

EAB) (1725)

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 12:07
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3570

EAB) (1725)

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:39
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 17:58
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	17:30 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 17:30
Temperature (xxx.x)	36.3 C
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	18:40 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 18:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 18:10 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 18:10

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

US3412022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

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

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	17:44 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 AUG 2020 17:44
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US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:35	26 AUG 2020 17:35
Nasopharyngeal Swab 2	No		

US3412022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

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 26 AUG 2020 18:44

PC Open Date & Time 26 AUG 2020 18:30

PC Close Date & Time 26 AUG 2020 21:00

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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	26 AUG 2020 23:44
PC Open Date & Time	26 AUG 2020 21:55
PC Close Date & Time	27 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

100.0 °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

27 AUG 2020 21:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 19:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

29 AUG 2020 22:46

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 19:51

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 18:44

PC Open Date & Time

26 AUG 2020 18:30

PC Close Date & Time

26 AUG 2020 21:00

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 23:45

PC Open Date & Time

26 AUG 2020 21:55

PC Close Date & Time

27 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 21:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 19:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 22:47

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 21:46

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:51

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 18:45
PC Open Date & Time	26 AUG 2020 18:30
PC Close Date & Time	26 AUG 2020 21:00

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 23:46
PC Open Date & Time	26 AUG 2020 21:55
PC Close Date & Time	27 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:00
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 19:45
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 22:47
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:45
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:51
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:51

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	VISIT3

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	13:30 (24 HR)
Collection date and time (derived)	23 SEP 2020 13:30

US3412022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:41:25

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 SEP 2020 15:21:33
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 16:24:31

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 OCT 2020 00:11:26
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 00:01:43
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 NOV 2020 14:36:14
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 106
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 NOV 2020 13:53:29
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 01:58:18
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 20:39:52
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 11:39:45

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 02:14:01

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 11:15:24

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 00:20:37

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 12:16:01

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 19:47:34
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 00:30:49

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 01:17:55

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 JAN 2021 08:46:04
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 194

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 04:04:46
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 00:02:51

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 23:36:00

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 00:41:06

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 08:58:09

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 236

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 23:14:39

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 19:46:20

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 08:04:44

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 00:02:38

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 11:01:06

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:51:09

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 285

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 299

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 320

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 327

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 348

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 362

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 383

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 397

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

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

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

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

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

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

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 ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 411

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 425

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 439

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 446

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 460

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 467

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2021 00:01
Patient Cloud Close Date & Time	30 NOV 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 DEC 2021 00:01
Patient Cloud Close Date & Time	07 DEC 2021 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 502

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

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 ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 530

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 565

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 579

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 586

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 628

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 635

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 649

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 684

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 698

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 705

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 712

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 719

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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19 JUL 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 733

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 747

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

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

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

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

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

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

Patient Cloud Open Date & Time	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	19 AUG 2022 00:01
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Patient Cloud Close Date & Time	23 AUG 2022 23:59
---	-------------------

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
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 ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3412022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:27:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:35:47

US3412022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT NOT CONTACTED DUE
TO SITE ERROR. SITE STAFF
INSTRUCTED TO COMPLETE
SAFETY CALLS ALONGSIDE
ILLNESS VISITS

US3412022

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT NOT CONTACTED DUE
TO SITE ERROR. SITE STAFF
INSTRUCTED TO COMPLETE
SAFETY CALLS ALONGSIDE
OPEN LABEL PHASE

US3412022

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	25 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	VISIT4
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US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 15:20
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)	69 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)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 FEB 2021
Collection time (00:00-23:59)	13:38 (24 HR)
Collection date and time (derived)	25 FEB 2021 13:38

US3412022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:07:17

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Date of Contact 12 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☒

Safety Call ☐

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

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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	08 NOV 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 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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EAB) (1725)

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Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 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 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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Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 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 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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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (4)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	37.1 C
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input 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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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 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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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

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 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 (7)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 12 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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 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 (8)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (9)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 2020
------	-------------

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"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
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"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 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 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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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 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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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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 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 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.4 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 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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 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 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (18)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input 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"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 NOV 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 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" 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 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	4 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	36.8 C	
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 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Date of Visit 12 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Date of Test 12 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐
No ☐

Start Date

End Date

Acute Renal Dysfunction? Yes ☐
No ☐

Start Date

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Hepatic Dysfunction? Yes ☐
No ☐

Start Date

Neurologic Dysfunction? Yes ☐
No ☐

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☐

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Date of Contact	23 DEC 2020
Time of Contact	11:20
Date and Time of Contact (derived)	23 DEC 2020 11:20
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 type="checkbox"/></div> <div>No <input checked="" type="checkbox"/></div>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	24 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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 (3)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 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 (3)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input 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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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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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Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.2 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input 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) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 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 (9)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	14 NOV 2020
Day 5	Yes	16 NOV 2020
Day 7	Yes	18 NOV 2020
Day 9	Yes	20 NOV 2020
Day 14	Yes	25 NOV 2020
Day 21	Yes	02 DEC 2020
Day 28	Yes	4 DEC 2020

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

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	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 11:35
Height (xxx.x)	186.5 cm
Weight (xxx.x)	152.9 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

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

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

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)	11:30 (24 HR)
Vital Signs Date and Time (derived)	23 DEC 2020 11:30
Height (xxx.x)	186.5 cm
Weight (xxx.x)	157.8 kg
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 15:06:57

Generated On: 09 Jun 2021 17:27:21

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 DEC 2020

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	SICKD28

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:06:56

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:15 (24 HR)
Vital Signs Date and Time (derived)	4 DEC 2020 11:15
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:06:55

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 15:06:55

Generated On: 09 Jun 2021 17:27:21

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 DEC 2020

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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	UNBLND_DECIDE

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	6 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Height	183.5 cm
Weight	157.0 kg
BMI (xxx.x)	46.62593

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Height	183.5 cm
Weight	157.0 kg
BMI (xxx.x)	46.62593
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)	6 JAN 2021
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 15:07
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Height	183.5 cm
Weight	157.0 kg
BMI (xxx.x)	46.62593
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)	6 JAN 2021
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	6 JAN 2021 15:58
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 6 JAN 2021

What was the treatment time? (00:00-23:59) 15:22 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 15:22

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:07:16

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	15:33 (24 HR)
Collection date and time (derived)	6 JAN 2021 15:33

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	15:14
Collection Date and Time (derived)	6 JAN 2021 15:14

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3412022

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

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)	25 FEB 2021
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:42
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

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)	25 FEB 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 15:20
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)	69 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412022

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

What was the treatment time? (00:00-23:59) 14:45 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 14:45

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

US3412022

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412022

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:22

Generated On: 09 Jun 2021 17:27:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412022

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:22 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 13:22
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412022

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3412022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 15:06:58

Generated On: 09 Jun 2021 17:27:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	25 MAR 2021 13:25

US3412022

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:25:25

Generated On: 09 Jun 2021 17:27:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412022

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

AEID	USA-US061-2020-MRNA-1273-P30 1000011
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	07 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

AEID

Adverse event

WORSENING TYPE II DIABETES
MELLITUS

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)

30 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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 type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	DIVERTICULITIS
Narrative	

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

WORSENING DIABETES (A1C 7.0
5MONTHS AGO AND MOST
RECENTLY 13 SAW PCP WHO
STARTED INSULIN., ONSET
30-10-2020 WHEN LAST A1C
DRAWN BY PCP. MODERATE,
NR, IMPROVING FBG.
RETURNING TO PCP ON
11-DEC-2020. WILL UPDATE
COVID19 AE UPON RECEIPT OF
LAB. NO SYMPTOMS.

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)	

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

AEID	USA-US061-2021-MRNA-1273-P30 1000006
Adverse event	DIVERTICULITIS
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)	28 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	02 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

OUR SITE WAS NOTIFIED ON
01-FEB-2021 BY SUBJECT OF HIS
ADMISSION INTO HOSPITAL ON
28-JAN-2021 FOR FEVER AND
ABDOMINAL PAIN. HE WAS
DIAGNOSED WITH
DIVERTICULITIS AND TREATED
WITH IV ANTIBIOTICS. HE WAS
DISCHARGED ON 02-FEB-2021
AND MEDICAL RECORDS ARE
BEING REQUESTED FOR
FURTHER FOLLOW UP.

SUBJECT PRESENTED TO ED AS
A 50Y/O MALE WITH HISTORY
OF HTN, T2DM, AND TOBACCO
ABUSE WITH ONSET OF LLQ
ABDOMINAL PAIN ON
28JAN2021. RECEIVED
MRNA-1273 (POST
UNBLINDING) ON 06JAN2021
AND 25FEB2021. INITIAL
PRESENTATION - FEBRILE 101.4,
ELEVATED WBC 13.2,
OTHERWISE VITALS STABLE.
PHYSICAL EXAM SIGNIFICANT
FOR MILD TO MODERATE
TENDERNESS LOCALLY TO THE
LEFT LOWER QUADRANT. LABS
AND STUDIES: 29JAN2021 - WBC
13.2 THOU/MCL WITH
REFERENCE RANGE 3.6-10.5
THOU/MCL; 30JAN2021 WBC
11.1; 31JAN2021 WBC 7.8;
01FEB2021 WBC 6.2; IMSGING -

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

CT WITH CONTRAST ABODMEN
PEVIS 29JAN2021
THICKENING/STRANDY
SIGMOID COLON WITH SMALL
LOCULE IN MISENTERY;
BLOOD CULTURE NEGATIVE,
UA-WNZ. SUBJECT WAS
MANAGED WITH
CONSERVATIVE TX WHICH
INCLUDED NPA AND THE
FOLLOWING MEDS: CIPRO IV,
FLAGYL IV, MORPHINE,
ZOTRAN, HEPARIN, TYLENOL,
MIRALAX, SENOKOT,
NOVOLOG. SUBJECT WAS
DISCHARGED WITH NEW
PRESCRIPTIONS HOWEVER HE
NEVER FILLED/TOOK ANY OF
THEM. THROUGH OUT
HOSPITAL STAY HIS PAIN
IMPROVED AND HE WAS
DISCHARGED ON 02FEB2021
WITH INSTRUCTIONS TO
FOLLOWUP FOR OUTPATIENT
COLONOSCOPY IN 6-8 WEEKS.
SUBJECT STATES ALL
SYMPTOMS HAVE FULLY
RESOLVED AND HE IS FEELING
WELL.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 15:06:55

Generated On: 09 Jun 2021 17:27:21

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DM2

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	2 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL EDEMA
SWELLING

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (3)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA -
CHOLESTEROL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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	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 DEC 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) 16 Apr 2021 13:29:03

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Name of Medication ESCITALOPRAN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY, 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 (5)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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)

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Name of Medication JANUMET XR

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 100/1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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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)	2 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

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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Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (8)

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Name of Medication CLARITAN (OTC)

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 (8)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1990
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) 16 Apr 2021 13:29:03

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Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication WORSENING TYPE 2 DIABETES

Dose per administration 15

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 (9)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 (10)

Data signed: (b) (4) 16 Apr 2021 13:29:03

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Name of Medication GLIPIZIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING TYPE 2 DIABETES

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 (10)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (11)

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Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	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="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

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 (12)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 FEB 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 (13)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication SENEKOT

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 17.2

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 (13)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 17

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 (14)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 FEB 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 (15)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)		01 FEB 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 (16)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication CIPRO

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

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) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	29 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)	01 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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)	01 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	3	
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 (18)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 (18)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 01 FEB 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 (19)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

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 (19)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	29 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)		29 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

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 (20)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	29 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)		29 JAN 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication DIVERTICULITIS

Dose per administration 5000

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) 16 Apr 2021 13:29:03

Generated On: 09 Jun 2021 17:27:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 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) 1 FEB 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"/>

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:30:30

Generated On: 09 Jun 2021 17:27:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:30:30

Generated On: 09 Jun 2021 17:27:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 JAN 2021	CT WITH CONTRAST ABODMEN PEVIS	Adverse Event	
29 JAN 2021	BLOOD CULTURE.	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:27:21

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 17:27:21

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2020-MRNA-1273-P301000011
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2020-MRNA-1273-P301000011
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/NOV/2020 16:48
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

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2020-MRNA-1273-P301000011
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/DEC/2020 17:23
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

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 13:52:21

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2020-MRNA-1273-P301000011
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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	14/DEC/2020 12:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/FEB/2021 12:28
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

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/FEB/2021 08:47
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

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/FEB/2021 09:02
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

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/MAR/2021 10:40
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

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 06:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 14:38:24

Generated On: 09 Jun 2021 17:27:21

SAEID	USA-US061-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/APR/2021 06:22
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

US3412022 (Prod: New Horizons Clinical Research)

US3412022

Form: Participant Creation

Generated On: 09 Jun 2021 17:27:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:54:02
User entered 'US3412022'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:19:16

US3412022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:06:41

US3412022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:19:17

US3412022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:06:41

US3412022

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'SCRN'	System	29 Jul 2020 19:06:41

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:19:18

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '50'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'YEARS'	System	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '50'	System	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:27:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:07:22

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jul 2020'	System	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2020'	System	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:08:42

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 18:19:17

US3412022

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:27:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'I'	System	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:27:21

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:27:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:01

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:12:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 13:12:05
Data point term sent to Coder	System	18 Nov 2020 13:11:22
User closed query ' DM-Coding: please split this term into 2 separate entries. 1)SLEEP APNEA 2)CPAP. One record per line. Please update this term in accordance with your answer.' (Site from System).	System	18 Nov 2020 13:11:05
Query ' DM-Coding: please split this term into 2 separate entries. 1)SLEEP APNEA 2)CPAP. One record per line. Please update this term in accordance with your answer.' answered with 'updated medical history per dm-coding.' (Site from System).	Melissa Fuson (b) (4)	18 Nov 2020 13:11:05
User entered 'SLEEP APNEA' reason for change: Data Entry Error	Melissa Fuson (b) (4)	18 Nov 2020 13:10:35
User opened query ' DM-Coding: please split this term into 2 separate entries. 1)SLEEP APNEA 2)CPAP. One record per line. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	18 Nov 2020 08:19:07
Data point term sent to Coder	System	17 Nov 2020 13:18:33
Coding entries removed.	Melissa Fuson (b) (4)	17 Nov 2020 13:18:10
User entered 'SLEEP APNEA (CPAP)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:18:10
User closed query 'Per MM: Please review and consider capturing SLEEP APNEA and CPAP separately. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 14:30:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 12:35:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 12:35:44

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	14 Sep 2020 12:35:07
Query 'Per MM: Please review and consider capturing SLEEP APNEA and CPAP separately. Update as appropriate.' answered with 'updated' (Site from DM).	Jacob sekinger (b) (4)	14 Sep 2020 12:35:01
Coding entries removed.	(b) (4)	
	Jacob sekinger (b) (4)	14 Sep 2020 12:34:52
User entered 'SLEEP APNEA' reason for change: Data Entry Error	(b) (4)	
	Jacob sekinger (b) (4)	14 Sep 2020 12:34:52
User opened query 'Per MM: Please review and consider capturing SLEEP APNEA and CPAP separately. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:10:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:15:15
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 22:15:15
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 14:35:57
User entered 'Sleep Apnea - CPAP'	(b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2005'	System	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2005'	System	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:24

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
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)	05 Aug 2020 14:36:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:36:59
Data point term sent to Coder	System	05 Aug 2020 14:35:57
User entered 'Hypertension'	(b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2010'	System	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2010'	System	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:40

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:37:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:37:00
Data point term sent to Coder	System	05 Aug 2020 14:36:00
User entered 'Diabetes type 2'	(b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2018'	System	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2018'	System	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:35:56

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:38:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:38:03
Data point term sent to Coder	System	05 Aug 2020 14:37:00
User entered 'Anxiety'	(b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2000'	System	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2000'	System	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:36:22

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:38:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 14:38:59
Data point term sent to Coder	System	05 Aug 2020 14:38:01
User entered 'Depression'	(b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2000'	System	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2000'	System	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:37:33

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User closed query 'Per MM, please update the MH condition to specify cause or medical diagnosis' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:49:53
Query 'Per MM, please update the MH condition to specify cause or medical diagnosis' answered with 'UNKNOWN' (Site from DM).	Mylene Asmar-Rios (b) (4)	30 Sep 2020 19:31:23
User opened query 'Per MM, please update the MH condition to specify cause or medical diagnosis' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:41:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Peripheral edema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:34:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:34:23
Data point term sent to Coder	System	05 Aug 2020 14:39:05
User entered 'Peripheral Edema Bilateral'	(b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2018'	System	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2018'	System	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	05 Aug 2020 14:38:14

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Central obesity, LLT: Abdominal obesity - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 12:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 12:37:40
Data point term sent to Coder	System	14 Sep 2020 12:37:09
User entered 'abdominal obesity'	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2018'	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2018'	System	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2018'	System	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	14 Sep 2020 12:36:26

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
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)	06 Oct 2020 14:12:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:12:09
Data point term sent to Coder	System	06 Oct 2020 13:35:11
User entered 'hyperlipidemia'	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'un Dec 2019'	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Dec 2019'	System	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2019'	System	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	06 Oct 2020 13:34:41

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Anterior cruciate ligament reconstruction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Oct 2020 15:39:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:39:07
Data point term sent to Coder	System	06 Oct 2020 13:36:14
User entered 'reconstructed ACL - left knee'	Jacob sekinger (b) (4) (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'un UNK 1990'	Jacob sekinger (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	Jacob sekinger (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'un UNK 1990'	Jacob sekinger (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 1990'	System	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '1990'	System	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 1990'	System	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '1990'	System	06 Oct 2020 13:36:09

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 14:46:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 14:46:46
Data point term sent to Coder	System	17 Nov 2020 13:17:32
User entered 'ALLERGIC RHINITIS - SEASONAL;'	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 1990'	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 1990'	System	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '1990'	System	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	17 Nov 2020 13:17:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Respiratory tract therapeutic procedures NEC, PT: Continuous positive airway pressure, LLT: Continuous positive airway pressure - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 13:14:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 13:14:04
Data point term sent to Coder	System	18 Nov 2020 13:13:22
User entered 'Continuous positive airway pressure'	Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'UN UNK 2005'	Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'Jan 2005'	System	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '2005'	System	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:27:21

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered empty.	System	18 Nov 2020 13:12:26

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '14:39'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered '29 Jul 2020 14:39'	System	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '185.7' cm reason for change: Data Entry Error	(b) (4)	05 Aug 2020 14:45:19
User entered '185' cm	(b) (4), (b) (6)	05 Aug 2020 14:43:49
DataPoint set to visible.	System	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '169.4' kg reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49
DataPoint set to visible.	System	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
Amendment Manager: User entered '49.12353'	System	16 Sep 2020 23:38:17
User entered '49.1'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49
DataPoint set to visible.	System	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'kg/m2'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49
DataPoint set to visible.	System	29 Jul 2020 19:09:03

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 18:25:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '36.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 04:24:54
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	19 Aug 2020 13:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:20:32
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 13:20:32
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Aug 2020 14:45:19
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 18:25:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'bpm'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 18:25:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'breaths/min'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 18:25:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '145' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'mmHg'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 18:25:00
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:45:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Aug 2020 14:45:19
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Aug 2020 14:45:19
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Aug 2020 14:43:49
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User entered 'mmHg'	System	05 Aug 2020 14:45:19
User entered empty.	System	05 Aug 2020 14:43:49

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52

US3412022

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52

US3412022

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:42:43

US3412022

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 13:36:17
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 21:52:31
User entered '29 Jul 2020'	(b) (4), (b) (6)	05 Aug 2020 14:42:43

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:27:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:37:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'lives in high risk county and with essential workers'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:43:25

US3412022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:25:28

US3412022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:25:28

US3412022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 19:25:28

US3412022

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'VISIT1'	System	29 Jul 2020 19:25:28

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:15:09

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:16:20
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:16:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 19:15:09
User entered '142277' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:15:09

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:15:09

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:07:14

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:07:14

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User closed query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:59:04
Query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' answered with 'as per source BMI >40 updated info' (Site from DM).	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:19:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:18:36
User opened query 'Per CDM: per sponsor review, BMI ≥ 40 kg/m2 yet participant is not recorded as at risk. Please reconcile' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:58:34
User entered 'No (N)'		29 Jul 2020 20:07:14

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:07:14

US3412022

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:27:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:07:14

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Pre-Dose (PREDOSE)'		05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered 'No (N)'	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '14:39' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '29 Jul 2020 14:39'	System	13 Aug 2020 19:02:21
User entered empty.	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '36.5' C reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '65' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'bpm'	System	13 Aug 2020 19:02:21
User entered empty.	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '16' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'breaths/min'	System	13 Aug 2020 19:02:21
User entered empty.	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '145' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	13 Aug 2020 19:02:21
User entered empty.	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '80' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 19:02:21
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	13 Aug 2020 19:02:21
User entered empty.	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Post-Dose (POSTDOSE)'		05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:03:00
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, post dose vitals were taken 30 after injection' (Site from System).		11 Aug 2020 15:03:21
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 14:41:16
User entered '16:02'	(b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '29 Jul 2020 16:02'	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'bpm'	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '12'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'breaths/min'	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '144'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '78'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	05 Aug 2020 14:41:16

US3412022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:39:31

US3412022

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:39:31

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '15:30'	(b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '29 Jul 2020 15:30'	System	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'ONCE'	System	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 20:08:33

US3412022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:24

US3412022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:24

US3412022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '14:57'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:24

US3412022

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '29 Jul 2020 14:57'	System	05 Aug 2020 14:40:24

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '14:52'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '29 Jul 2020 14:52'	System	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	05 Aug 2020 14:40:07

US3412022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 14:39:52

US3412022

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	05 Aug 2020 14:39:52

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:10:23', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e4c0bdf6-7afc-42dd-8f19-bf9409547fd4'	System	29 Jul 2020 20:10:54
User entered 'Yes (Y)'	System	29 Jul 2020 20:10:54

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:10:28', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e4c0bdf6-7afc-42dd-8f19-bf9409547fd4'	System	29 Jul 2020 20:10:54
User entered '98.4'	System	29 Jul 2020 20:10:54

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:10:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e4c0bdf6-7afc-42dd-8f19-bf9409547fd4'	System	29 Jul 2020 20:10:54
User entered 'No (N)'	System	29 Jul 2020 20:10:54

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:10:49', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e4c0bdf6-7afc-42dd-8f19-bf9409547fd4'	System	29 Jul 2020 20:10:54
User entered '29 Jul 2020 16:10'	System	29 Jul 2020 20:10:54

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 18:20'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '32524043-d8c7-4ef5-9101-d5fc65080bc1'	System	30 Jul 2020 05:30:40
User entered 'Yes (Y)'	System	30 Jul 2020 05:30:40

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '32524043-d8c7-4ef5-9101-d5fc65080bc1'	System	30 Jul 2020 05:30:40
User entered '96.7'	System	30 Jul 2020 05:30:40

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:30', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '32524043-d8c7-4ef5-9101-d5fc65080bc1'	System	30 Jul 2020 05:30:40
User entered 'No (N)'	System	30 Jul 2020 05:30:40

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '32524043-d8c7-4ef5-9101-d5fc65080bc1'	System	30 Jul 2020 05:30:40
User entered '30 Jul 2020 01:30'	System	30 Jul 2020 05:30:40

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 19:15'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 2'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '9f0df7d7-1824-4eb1-8123-db4b3527c6ad'	System	31 Jul 2020 01:14:20
User entered 'Yes (Y)'	System	31 Jul 2020 01:14:20

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:10', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '9f0df7d7-1824-4eb1-8123-db4b3527c6ad'	System	31 Jul 2020 01:14:20
User entered '97.7'	System	31 Jul 2020 01:14:20

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:13', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '9f0df7d7-1824-4eb1-8123-db4b3527c6ad'	System	31 Jul 2020 01:14:20
User entered 'No (N)'	System	31 Jul 2020 01:14:20

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '9f0df7d7-1824-4eb1-8123-db4b3527c6ad'	System	31 Jul 2020 01:14:20
User entered '30 Jul 2020 21:14'	System	31 Jul 2020 01:14:20

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 3'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:17', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'bc6f79cc-2b68-4556-9429-aba02b96d5f8'	System	31 Jul 2020 21:12:32
User entered 'Yes (Y)'	System	31 Jul 2020 21:12:32

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:23', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'bc6f79cc-2b68-4556-9429-aba02b96d5f8'	System	31 Jul 2020 21:12:32
User entered '97.7'	System	31 Jul 2020 21:12:32

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'bc6f79cc-2b68-4556-9429-aba02b96d5f8'	System	31 Jul 2020 21:12:32
User entered 'No (N)'	System	31 Jul 2020 21:12:32

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'bc6f79cc-2b68-4556-9429-aba02b96d5f8'	System	31 Jul 2020 21:12:32
User entered '31 Jul 2020 17:12'	System	31 Jul 2020 21:12:32

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 4'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:25', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '58ba1268-89e0-43a8-accd-9bf06f4edae9'	System	02 Aug 2020 04:12:42
User entered 'Yes (Y)'	System	02 Aug 2020 04:12:42

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '58ba1268-89e0-43a8-accd-9bf06f4edae9'	System	02 Aug 2020 04:12:42
User entered '98.0'	System	02 Aug 2020 04:12:42

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '58ba1268-89e0-43a8-accd-9bf06f4edae9'	System	02 Aug 2020 04:12:42
User entered 'No (N)'	System	02 Aug 2020 04:12:42

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '58ba1268-89e0-43a8-accd-9bf06f4edae9'	System	02 Aug 2020 04:12:42
User entered '02 Aug 2020 00:12'	System	02 Aug 2020 04:12:42

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 5'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '438e2cf5-4b6d-45c1-a25b-e88e49af5245'	System	02 Aug 2020 16:08:08
User entered 'Yes (Y)'	System	02 Aug 2020 16:08:08

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '438e2cf5-4b6d-45c1-a25b-e88e49af5245'	System	02 Aug 2020 16:08:08
User entered '97.3'	System	02 Aug 2020 16:08:08

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:08:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '438e2cf5-4b6d-45c1-a25b-e88e49af5245'	System	02 Aug 2020 16:08:08
User entered 'No (N)'	System	02 Aug 2020 16:08:08

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:08:05', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '438e2cf5-4b6d-45c1-a25b-e88e49af5245'	System	02 Aug 2020 16:08:08
User entered '02 Aug 2020 12:08'	System	02 Aug 2020 16:08:08

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 6'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e2e64f19-f04e-404c-88e6-de7b734a0fed'	System	03 Aug 2020 16:39:39
User entered 'Yes (Y)'	System	03 Aug 2020 16:39:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:27', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e2e64f19-f04e-404c-88e6-de7b734a0fed'	System	03 Aug 2020 16:39:39
User entered '97.9'	System	03 Aug 2020 16:39:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e2e64f19-f04e-404c-88e6-de7b734a0fed'	System	03 Aug 2020 16:39:39
User entered 'No (N)'	System	03 Aug 2020 16:39:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:35', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e2e64f19-f04e-404c-88e6-de7b734a0fed'	System	03 Aug 2020 16:39:39
User entered '03 Aug 2020 12:39'	System	03 Aug 2020 16:39:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 7'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '98540714-24e5-43a7-a68c-8ada0bb37ea8'	System	04 Aug 2020 21:57:39
User entered 'Yes (Y)'	System	04 Aug 2020 21:57:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '98540714-24e5-43a7-a68c-8ada0bb37ea8'	System	04 Aug 2020 21:57:39
User entered '97.9'	System	04 Aug 2020 21:57:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '98540714-24e5-43a7-a68c-8ada0bb37ea8'	System	04 Aug 2020 21:57:39
User entered 'No (N)'	System	04 Aug 2020 21:57:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '98540714-24e5-43a7-a68c-8ada0bb37ea8'	System	04 Aug 2020 21:57:39
User entered '04 Aug 2020 17:57'	System	04 Aug 2020 21:57:39

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5fbfbc8f-e1f6-4baf-b782-08931a51790c'	System	29 Jul 2020 20:11:35
User entered 'None (1)'	System	29 Jul 2020 20:11:35

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:11', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5fbfbc8f-e1f6-4baf-b782-08931a51790c'	System	29 Jul 2020 20:11:35
User entered 'No (N)'	System	29 Jul 2020 20:11:35

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:15', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5fbfbc8f-e1f6-4baf-b782-08931a51790c'	System	29 Jul 2020 20:11:35
User entered 'No (N)'	System	29 Jul 2020 20:11:35

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5fbfbc8f-e1f6-4baf-b782-08931a51790c'	System	29 Jul 2020 20:11:35
User entered 'None (1)'	System	29 Jul 2020 20:11:35

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5fbfbc8f-e1f6-4baf-b782-08931a51790c'	System	29 Jul 2020 20:11:35
User entered '29 Jul 2020 16:11'	System	29 Jul 2020 20:11:35

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 18:20'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:41', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b01f9924-08c6-4aa0-86cb-28531d671a94'	System	30 Jul 2020 05:31:28
User entered 'None (1)'	System	30 Jul 2020 05:31:28

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b01f9924-08c6-4aa0-86cb-28531d671a94'	System	30 Jul 2020 05:31:28
User entered 'No (N)'	System	30 Jul 2020 05:31:28

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:52', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b01f9924-08c6-4aa0-86cb-28531d671a94'	System	30 Jul 2020 05:31:28
User entered 'No (N)'	System	30 Jul 2020 05:31:28

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:30:56', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b01f9924-08c6-4aa0-86cb-28531d671a94'	System	30 Jul 2020 05:31:28
User entered 'None (1)'	System	30 Jul 2020 05:31:28

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b01f9924-08c6-4aa0-86cb-28531d671a94'	System	30 Jul 2020 05:31:28
User entered '30 Jul 2020 01:31'	System	30 Jul 2020 05:31:28

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 19:15'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 2'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:41', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e26b854d-b713-4321-9f2f-1ac2f4bd6507'	System	31 Jul 2020 01:15:15
User entered 'None (1)'	System	31 Jul 2020 01:15:15

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e26b854d-b713-4321-9f2f-1ac2f4bd6507'	System	31 Jul 2020 01:15:15
User entered 'No (N)'	System	31 Jul 2020 01:15:15

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:14:49', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e26b854d-b713-4321-9f2f-1ac2f4bd6507'	System	31 Jul 2020 01:15:15
User entered 'No (N)'	System	31 Jul 2020 01:15:15

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e26b854d-b713-4321-9f2f-1ac2f4bd6507'	System	31 Jul 2020 01:15:15
User entered 'None (1)'	System	31 Jul 2020 01:15:15

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e26b854d-b713-4321-9f2f-1ac2f4bd6507'	System	31 Jul 2020 01:15:15
User entered '30 Jul 2020 21:15'	System	31 Jul 2020 01:15:15

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 3'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7a8be154-e227-4a1c-a137-2c560977a097'	System	31 Jul 2020 21:12:50
User entered 'None (1)'	System	31 Jul 2020 21:12:50

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7a8be154-e227-4a1c-a137-2c560977a097'	System	31 Jul 2020 21:12:50
User entered 'No (N)'	System	31 Jul 2020 21:12:50

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7a8be154-e227-4a1c-a137-2c560977a097'	System	31 Jul 2020 21:12:50
User entered 'No (N)'	System	31 Jul 2020 21:12:50

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:43', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7a8be154-e227-4a1c-a137-2c560977a097'	System	31 Jul 2020 21:12:50
User entered 'None (1)'	System	31 Jul 2020 21:12:50

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7a8be154-e227-4a1c-a137-2c560977a097'	System	31 Jul 2020 21:12:50
User entered '31 Jul 2020 17:12'	System	31 Jul 2020 21:12:50

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 4'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '1b190d69-9df8-4af0-97f4-5ad8402639c6'	System	02 Aug 2020 04:12:13
User entered 'None (1)'	System	02 Aug 2020 04:12:13

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '1b190d69-9df8-4af0-97f4-5ad8402639c6'	System	02 Aug 2020 04:12:13
User entered 'No (N)'	System	02 Aug 2020 04:12:13

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '1b190d69-9df8-4af0-97f4-5ad8402639c6'	System	02 Aug 2020 04:12:13
User entered 'No (N)'	System	02 Aug 2020 04:12:13

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '1b190d69-9df8-4af0-97f4-5ad8402639c6'	System	02 Aug 2020 04:12:13
User entered 'None (1)'	System	02 Aug 2020 04:12:13

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:12:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '1b190d69-9df8-4af0-97f4-5ad8402639c6'	System	02 Aug 2020 04:12:13
User entered '02 Aug 2020 00:12'	System	02 Aug 2020 04:12:13

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 5'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:06:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'da63e636-0c11-4b85-952b-8adcd08f7a84'	System	02 Aug 2020 16:07:02
User entered 'None (1)'	System	02 Aug 2020 16:07:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:06:48', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'da63e636-0c11-4b85-952b-8adcd08f7a84'	System	02 Aug 2020 16:07:02
User entered 'No (N)'	System	02 Aug 2020 16:07:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:06:50', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'da63e636-0c11-4b85-952b-8adcd08f7a84'	System	02 Aug 2020 16:07:02
User entered 'No (N)'	System	02 Aug 2020 16:07:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:06:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'da63e636-0c11-4b85-952b-8adcd08f7a84'	System	02 Aug 2020 16:07:02
User entered 'None (1)'	System	02 Aug 2020 16:07:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:06:58', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'da63e636-0c11-4b85-952b-8adcd08f7a84'	System	02 Aug 2020 16:07:02
User entered '02 Aug 2020 12:06'	System	02 Aug 2020 16:07:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 6'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0171f1b8-e8ef-48a7-a370-9625b0515aeb'	System	03 Aug 2020 16:38:51
User entered 'None (1)'	System	03 Aug 2020 16:38:51

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0171f1b8-e8ef-48a7-a370-9625b0515aeb'	System	03 Aug 2020 16:38:51
User entered 'No (N)'	System	03 Aug 2020 16:38:51

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0171f1b8-e8ef-48a7-a370-9625b0515aeb'	System	03 Aug 2020 16:38:51
User entered 'No (N)'	System	03 Aug 2020 16:38:51

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0171f1b8-e8ef-48a7-a370-9625b0515aeb'	System	03 Aug 2020 16:38:51
User entered 'None (1)'	System	03 Aug 2020 16:38:51

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:48', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0171f1b8-e8ef-48a7-a370-9625b0515aeb'	System	03 Aug 2020 16:38:51
User entered '03 Aug 2020 12:38'	System	03 Aug 2020 16:38:51

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 7'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '79dd9b6b-6869-47ef-b1b9-3caf27a6d241'	System	04 Aug 2020 21:58:02
User entered 'None (1)'	System	04 Aug 2020 21:58:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '79dd9b6b-6869-47ef-b1b9-3caf27a6d241'	System	04 Aug 2020 21:58:02
User entered 'No (N)'	System	04 Aug 2020 21:58:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '79dd9b6b-6869-47ef-b1b9-3caf27a6d241'	System	04 Aug 2020 21:58:02
User entered 'No (N)'	System	04 Aug 2020 21:58:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:54', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '79dd9b6b-6869-47ef-b1b9-3caf27a6d241'	System	04 Aug 2020 21:58:02
User entered 'None (1)'	System	04 Aug 2020 21:58:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:57:58', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '79dd9b6b-6869-47ef-b1b9-3caf27a6d241'	System	04 Aug 2020 21:58:02
User entered '04 Aug 2020 17:57'	System	04 Aug 2020 21:58:02

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:49', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:11:56', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'None (0)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:12:02', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered 'No (N)'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-29T16:12:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'f7c9a447-a89c-4b11-b07e-fd6a0db19e4d'	System	29 Jul 2020 20:12:08
User entered '29 Jul 2020 16:12'	System	29 Jul 2020 20:12:08

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 18:20'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:15', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'None (0)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:40', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered 'No (N)'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T01:31:43', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7de3e2f0-0cfc-4d55-976a-e61960f0aa15'	System	30 Jul 2020 05:31:45
User entered '30 Jul 2020 01:31'	System	30 Jul 2020 05:31:45

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Jul 2020 19:15'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 2'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'None (0)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:30', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered 'No (N)'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-30T21:15:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3c146fe7-e541-48af-897c-f18aa95a7da7'	System	31 Jul 2020 01:15:41
User entered '30 Jul 2020 21:15'	System	31 Jul 2020 01:15:41

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 3'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:54', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:12:59', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'None (0)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:09', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered 'No (N)'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-07-31T17:13:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'de1ca349-f193-4b4d-8fca-d8c5db27d284'	System	31 Jul 2020 21:13:15
User entered '31 Jul 2020 17:13'	System	31 Jul 2020 21:13:15

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 4'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:40', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'None (0)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered 'No (N)'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T00:11:50', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd5577bed-375d-4ed9-a506-1dc2623b22c5'	System	02 Aug 2020 04:11:53
User entered '02 Aug 2020 00:11'	System	02 Aug 2020 04:11:53

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 5'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:09', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:11', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'None (0)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:28', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered 'No (N)'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-02T12:07:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '12d06bef-82b5-4402-843c-f1e4def27512'	System	02 Aug 2020 16:07:36
User entered '02 Aug 2020 12:07'	System	02 Aug 2020 16:07:36

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 6'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:55', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:38:59', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'None (0)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered 'No (N)'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-03T12:39:11', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e3e46d5f-9325-4400-b09c-aa74e196d454'	System	03 Aug 2020 16:39:14
User entered '03 Aug 2020 12:39'	System	03 Aug 2020 16:39:14

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 7'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:10', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:15', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:18', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:20', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'None (0)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered 'No (N)'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-04T17:58:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'caaa2e4d-21d2-4c8c-af0f-fc1f844f2ca2'	System	04 Aug 2020 21:58:32
User entered '04 Aug 2020 17:58'	System	04 Aug 2020 21:58:32

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 20:08:33

US3412022

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Aug 2020 22:24:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:24:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Aug 2020 22:24:18
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:24:09
User entered empty.	(b) (4), (b) (6)	12 Aug 2020 22:24:09

US3412022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 22:24:09

US3412022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Aug 2020 22:24:09

US3412022

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Aug 2020 22:24:09

US3412022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 11:53:32
User entered 'No (N)'	(b) (4), (b) (6)	12 Aug 2020 22:23:09

US3412022

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	20 Aug 2020 11:53:32
User entered empty.	System	12 Aug 2020 22:23:09

US3412022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:53:45

US3412022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '12 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:53:45

US3412022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:53:45

US3412022

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:53:45

US3412022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:53:52

US3412022

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User entered 'I'	System	20 Aug 2020 11:53:52

US3412022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:55:15

US3412022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:55:15

US3412022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:55:15

US3412022

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:55:15

US3412022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 11:55:20

US3412022

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User entered 'I'	System	20 Aug 2020 11:55:20

US3412022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:52:31

US3412022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:52:31

US3412022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:52:31

US3412022

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'VISIT2'	System	26 Aug 2020 21:52:31

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '17:30'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '26 Aug 2020 17:30'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '36.3' C	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '84'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'bpm'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '16'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'breaths/min'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '138'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '78'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '18:40'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '26 Aug 2020 18:40'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '98.2' F	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '82'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'bpm'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '18'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'breaths/min'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '130'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '78'	Jacob sekinger (b) (4)	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'mmHg'	System	14 Sep 2020 12:55:32

US3412022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:56:18

US3412022

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	14 Sep 2020 12:56:18

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '18:10'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '26 Aug 2020 18:10'	System	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'ONCE'	System	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 22:12:35

US3412022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:57:42

US3412022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	14 Sep 2020 12:57:42

US3412022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '17:44'	Jacob sekinger (b) (4)	14 Sep 2020 12:57:42

US3412022

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '26 Aug 2020 17:44'	System	14 Sep 2020 12:57:42

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:27:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '17:35'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '26 Aug 2020 17:35'	System	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Jacob sekinger (b) (4)	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	14 Sep 2020 12:58:06

US3412022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:36

US3412022

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '1'	System	02 Sep 2020 20:40:36

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a00ed516-830c-45bd-b5b1-5f33a194328b'	System	26 Aug 2020 22:44:24
User entered 'Yes (Y)'	System	26 Aug 2020 22:44:24

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a00ed516-830c-45bd-b5b1-5f33a194328b'	System	26 Aug 2020 22:44:24
User entered '98.2'	System	26 Aug 2020 22:44:24

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a00ed516-830c-45bd-b5b1-5f33a194328b'	System	26 Aug 2020 22:44:24
User entered 'No (N)'	System	26 Aug 2020 22:44:24

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:20', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a00ed516-830c-45bd-b5b1-5f33a194328b'	System	26 Aug 2020 22:44:24
User entered '26 Aug 2020 18:44'	System	26 Aug 2020 22:44:24

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 18:30'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '68ea3319-b003-409c-8fde-6391bd24c82b'	System	27 Aug 2020 03:44:40
User entered 'Yes (Y)'	System	27 Aug 2020 03:44:40

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '68ea3319-b003-409c-8fde-6391bd24c82b'	System	27 Aug 2020 03:44:40
User entered '98.7'	System	27 Aug 2020 03:44:40

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '68ea3319-b003-409c-8fde-6391bd24c82b'	System	27 Aug 2020 03:44:40
User entered 'No (N)'	System	27 Aug 2020 03:44:40

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '68ea3319-b003-409c-8fde-6391bd24c82b'	System	27 Aug 2020 03:44:40
User entered '26 Aug 2020 23:44'	System	27 Aug 2020 03:44:40

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:55'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 2'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3e94e0a3-04ec-4ff8-a377-66eeca7cc61'	System	28 Aug 2020 01:59:35
User entered 'Yes (Y)'	System	28 Aug 2020 01:59:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:25', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3e94e0a3-04ec-4ff8-a377-66eeca7cc61'	System	28 Aug 2020 01:59:35
User entered '100.0'	System	28 Aug 2020 01:59:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:27', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3e94e0a3-04ec-4ff8-a377-66eeca7cc61'	System	28 Aug 2020 01:59:35
User entered 'No (N)'	System	28 Aug 2020 01:59:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3e94e0a3-04ec-4ff8-a377-66eeca7cc61'	System	28 Aug 2020 01:59:35
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 01:59:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 3'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:44:55', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'eced92e3-6e3f-4a6a-b07a-d4f2c4981f76'	System	28 Aug 2020 23:45:19
User entered 'Yes (Y)'	System	28 Aug 2020 23:45:19

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'eced92e3-6e3f-4a6a-b07a-d4f2c4981f76'	System	28 Aug 2020 23:45:19
User entered '98.6'	System	28 Aug 2020 23:45:19

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'eced92e3-6e3f-4a6a-b07a-d4f2c4981f76'	System	28 Aug 2020 23:45:19
User entered 'No (N)'	System	28 Aug 2020 23:45:19

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:13', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'eced92e3-6e3f-4a6a-b07a-d4f2c4981f76'	System	28 Aug 2020 23:45:19
User entered '28 Aug 2020 19:45'	System	28 Aug 2020 23:45:19

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 4'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:18', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b12610f8-4a49-4dcd-a0d8-d53b91e1818e'	System	30 Aug 2020 02:46:43
User entered 'Yes (Y)'	System	30 Aug 2020 02:46:43

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b12610f8-4a49-4dcd-a0d8-d53b91e1818e'	System	30 Aug 2020 02:46:43
User entered '98.1'	System	30 Aug 2020 02:46:43

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b12610f8-4a49-4dcd-a0d8-d53b91e1818e'	System	30 Aug 2020 02:46:43
User entered 'No (N)'	System	30 Aug 2020 02:46:43

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:40', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b12610f8-4a49-4dcd-a0d8-d53b91e1818e'	System	30 Aug 2020 02:46:43
User entered '29 Aug 2020 22:46'	System	30 Aug 2020 02:46:43

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 5'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '08712933-d151-4528-bad2-0b2c0a83d82f'	System	31 Aug 2020 01:47:08
User entered 'Yes (Y)'	System	31 Aug 2020 01:47:08

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:56', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '08712933-d151-4528-bad2-0b2c0a83d82f'	System	31 Aug 2020 01:47:08
User entered '99.0'	System	31 Aug 2020 01:47:08

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:59', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '08712933-d151-4528-bad2-0b2c0a83d82f'	System	31 Aug 2020 01:47:08
User entered 'No (N)'	System	31 Aug 2020 01:47:08

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:47:02', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '08712933-d151-4528-bad2-0b2c0a83d82f'	System	31 Aug 2020 01:47:08
User entered '30 Aug 2020 21:47'	System	31 Aug 2020 01:47:08

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 6'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:50:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '339a6eb8-df81-4c05-b899-44f5be9615ba'	System	31 Aug 2020 23:51:10
User entered 'Yes (Y)'	System	31 Aug 2020 23:51:10

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:50:56', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '339a6eb8-df81-4c05-b899-44f5be9615ba'	System	31 Aug 2020 23:51:10
User entered '99.0'	System	31 Aug 2020 23:51:10

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:50:58', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '339a6eb8-df81-4c05-b899-44f5be9615ba'	System	31 Aug 2020 23:51:10
User entered 'No (N)'	System	31 Aug 2020 23:51:10

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:07', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '339a6eb8-df81-4c05-b899-44f5be9615ba'	System	31 Aug 2020 23:51:10
User entered '31 Aug 2020 19:51'	System	31 Aug 2020 23:51:10

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 7'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:33', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a15af8-4c60-4edd-a20b-b22bc8e61c53'	System	26 Aug 2020 22:44:53
User entered 'None (1)'	System	26 Aug 2020 22:44:53

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a15af8-4c60-4edd-a20b-b22bc8e61c53'	System	26 Aug 2020 22:44:53
User entered 'No (N)'	System	26 Aug 2020 22:44:53

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a15af8-4c60-4edd-a20b-b22bc8e61c53'	System	26 Aug 2020 22:44:53
User entered 'No (N)'	System	26 Aug 2020 22:44:53

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a15af8-4c60-4edd-a20b-b22bc8e61c53'	System	26 Aug 2020 22:44:53
User entered 'None (1)'	System	26 Aug 2020 22:44:53

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:50', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a15af8-4c60-4edd-a20b-b22bc8e61c53'	System	26 Aug 2020 22:44:53
User entered '26 Aug 2020 18:44'	System	26 Aug 2020 22:44:53

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 18:30'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e5c02056-1ec2-434b-aa0b-2adf9437c68f'	System	27 Aug 2020 03:45:17
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 03:45:17

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:44:56', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e5c02056-1ec2-434b-aa0b-2adf9437c68f'	System	27 Aug 2020 03:45:17
User entered 'No (N)'	System	27 Aug 2020 03:45:17

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e5c02056-1ec2-434b-aa0b-2adf9437c68f'	System	27 Aug 2020 03:45:17
User entered 'No (N)'	System	27 Aug 2020 03:45:17

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:09', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e5c02056-1ec2-434b-aa0b-2adf9437c68f'	System	27 Aug 2020 03:45:17
User entered 'None (1)'	System	27 Aug 2020 03:45:17

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e5c02056-1ec2-434b-aa0b-2adf9437c68f'	System	27 Aug 2020 03:45:17
User entered '26 Aug 2020 23:45'	System	27 Aug 2020 03:45:17

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:55'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 2'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '87f10c6b-5af5-4bb5-9885-cdd7ccf77773'	System	28 Aug 2020 02:00:12
User entered 'None (1)'	System	28 Aug 2020 02:00:12

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:41', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '87f10c6b-5af5-4bb5-9885-cdd7ccf77773'	System	28 Aug 2020 02:00:12
User entered 'No (N)'	System	28 Aug 2020 02:00:12

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '87f10c6b-5af5-4bb5-9885-cdd7ccf77773'	System	28 Aug 2020 02:00:12
User entered 'No (N)'	System	28 Aug 2020 02:00:12

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:48', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '87f10c6b-5af5-4bb5-9885-cdd7ccf77773'	System	28 Aug 2020 02:00:12
User entered 'None (1)'	System	28 Aug 2020 02:00:12

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:52', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '87f10c6b-5af5-4bb5-9885-cdd7ccf77773'	System	28 Aug 2020 02:00:12
User entered '27 Aug 2020 21:59'	System	28 Aug 2020 02:00:12

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 3'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:17', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0ef39007-48e9-43d5-8a72-a79734a53a6e'	System	28 Aug 2020 23:45:30
User entered 'None (1)'	System	28 Aug 2020 23:45:30

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0ef39007-48e9-43d5-8a72-a79734a53a6e'	System	28 Aug 2020 23:45:30
User entered 'No (N)'	System	28 Aug 2020 23:45:30

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0ef39007-48e9-43d5-8a72-a79734a53a6e'	System	28 Aug 2020 23:45:30
User entered 'No (N)'	System	28 Aug 2020 23:45:30

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0ef39007-48e9-43d5-8a72-a79734a53a6e'	System	28 Aug 2020 23:45:30
User entered 'None (1)'	System	28 Aug 2020 23:45:30

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:27', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0ef39007-48e9-43d5-8a72-a79734a53a6e'	System	28 Aug 2020 23:45:30
User entered '28 Aug 2020 19:45'	System	28 Aug 2020 23:45:30

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 4'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd0636ffe-9993-4f0f-8674-7339e4c42ab2'	System	30 Aug 2020 02:47:09
User entered 'None (1)'	System	30 Aug 2020 02:47:09

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:46:58', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd0636ffe-9993-4f0f-8674-7339e4c42ab2'	System	30 Aug 2020 02:47:09
User entered 'No (N)'	System	30 Aug 2020 02:47:09

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd0636ffe-9993-4f0f-8674-7339e4c42ab2'	System	30 Aug 2020 02:47:09
User entered 'No (N)'	System	30 Aug 2020 02:47:09

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd0636ffe-9993-4f0f-8674-7339e4c42ab2'	System	30 Aug 2020 02:47:09
User entered 'None (1)'	System	30 Aug 2020 02:47:09

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:07', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'd0636ffe-9993-4f0f-8674-7339e4c42ab2'	System	30 Aug 2020 02:47:09
User entered '29 Aug 2020 22:47'	System	30 Aug 2020 02:47:09

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 5'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '65224da0-5109-4ead-9083-072955ddbd5c'	System	31 Aug 2020 01:46:26
User entered 'None (1)'	System	31 Aug 2020 01:46:26

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:10', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '65224da0-5109-4ead-9083-072955ddbd5c'	System	31 Aug 2020 01:46:26
User entered 'No (N)'	System	31 Aug 2020 01:46:26

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '65224da0-5109-4ead-9083-072955ddbd5c'	System	31 Aug 2020 01:46:26
User entered 'No (N)'	System	31 Aug 2020 01:46:26

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '65224da0-5109-4ead-9083-072955ddbd5c'	System	31 Aug 2020 01:46:26
User entered 'None (1)'	System	31 Aug 2020 01:46:26

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:46:23', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '65224da0-5109-4ead-9083-072955ddbd5c'	System	31 Aug 2020 01:46:26
User entered '30 Aug 2020 21:46'	System	31 Aug 2020 01:46:26

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 6'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:11', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3f291507-c00a-4c57-ad0e-200549e28cf6'	System	31 Aug 2020 23:51:25
User entered 'None (1)'	System	31 Aug 2020 23:51:25

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3f291507-c00a-4c57-ad0e-200549e28cf6'	System	31 Aug 2020 23:51:25
User entered 'No (N)'	System	31 Aug 2020 23:51:25

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3f291507-c00a-4c57-ad0e-200549e28cf6'	System	31 Aug 2020 23:51:25
User entered 'No (N)'	System	31 Aug 2020 23:51:25

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3f291507-c00a-4c57-ad0e-200549e28cf6'	System	31 Aug 2020 23:51:25
User entered 'None (1)'	System	31 Aug 2020 23:51:25

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3f291507-c00a-4c57-ad0e-200549e28cf6'	System	31 Aug 2020 23:51:25
User entered '31 Aug 2020 19:51'	System	31 Aug 2020 23:51:25

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 7'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:44:59', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:03', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:06', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:10', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'None (0)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered 'No (N)'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T18:45:22', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc670282-0725-4b28-a4dc-3cbdc04e317'	System	26 Aug 2020 22:45:29
User entered '26 Aug 2020 18:45'	System	26 Aug 2020 22:45:29

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 18:30'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:46', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:54', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'None (0)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:45:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered 'No (N)'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-26T23:46:02', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '18682888-7b2b-4778-970d-5f16f03ccc70'	System	27 Aug 2020 03:46:06
User entered '26 Aug 2020 23:46'	System	27 Aug 2020 03:46:06

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '26 Aug 2020 21:55'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 2'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T21:59:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'None (0)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'None (0)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'None (0)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'None (0)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:19', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'None (0)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered 'No (N)'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-27T22:00:30', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '52f33287-a2ad-4449-a57a-e4fcd34941e3'	System	28 Aug 2020 02:00:42
User entered '27 Aug 2020 22:00'	System	28 Aug 2020 02:00:42

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 3'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:33', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'None (0)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered 'No (N)'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-28T19:45:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'e850606e-6615-494c-8dab-e02716182779'	System	28 Aug 2020 23:45:49
User entered '28 Aug 2020 19:45'	System	28 Aug 2020 23:45:49

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 4'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:12', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:16', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:18', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:20', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:21', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'None (0)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:25', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered 'No (N)'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-29T22:47:28', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5ab159da-3789-49b9-ad5a-3d92faba956d'	System	30 Aug 2020 02:47:30
User entered '29 Aug 2020 22:47'	System	30 Aug 2020 02:47:30

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 5'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:46', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:48', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:50', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:52', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'None (0)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:55', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered 'No (N)'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-30T21:45:58', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '57ca4163-f48b-4fab-b771-f3cdef5f6518'	System	31 Aug 2020 01:46:02
User entered '30 Aug 2020 21:45'	System	31 Aug 2020 01:46:02

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 6'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:33', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:38', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'None (0)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:43', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered 'No (N)'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-08-31T19:51:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b26f9d99-a254-4225-a011-e66f939e68c0'	System	31 Aug 2020 23:51:50
User entered '31 Aug 2020 19:51'	System	31 Aug 2020 23:51:50

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	26 Aug 2020 22:12:35
User entered 'Day 7'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 22:12:35

US3412022

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:27:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 22:12:35

US3412022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:49

US3412022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:49

US3412022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:49

US3412022

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:49

US3412022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 20:40:53

US3412022

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:21
User entered 'I'	System	02 Sep 2020 20:40:53

US3412022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 19:17:28

US3412022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '9 Sep 2020'	Mason Urban (b) (4)	09 Sep 2020 19:17:28

US3412022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Sep 2020 19:17:28

US3412022

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Mason Urban (b) (4)	09 Sep 2020 19:17:28

US3412022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 19:17:45

US3412022

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	09 Sep 2020 19:17:45

US3412022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 18:09:24

US3412022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '16 Sep 2020'	Mason Urban (b) (4)	16 Sep 2020 18:09:24

US3412022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	16 Sep 2020 18:09:24

US3412022

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Mason Urban (b) (4)	16 Sep 2020 18:09:24

US3412022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 18:09:28

US3412022

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	16 Sep 2020 18:09:28

US3412022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:09

US3412022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '23 Sep 2020'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:09

US3412022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:09

US3412022

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'VISIT3'	System	30 Sep 2020 15:45:09

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered empty.	System	30 Sep 2020 15:45:40

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24

US3412022

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24

US3412022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:28:20
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:59

US3412022

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:28:20
User entered '23 Sep 2020'	Melissa Fuson (b) (4)	30 Sep 2020 15:45:59

US3412022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Sep 2020 15:46:19

US3412022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '23 Sep 2020'	Melissa Fuson (b) (4)	30 Sep 2020 15:46:19

US3412022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered '13:30'	Melissa Fuson (b) (4)	30 Sep 2020 15:46:19

US3412022

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered '23 Sep 2020 13:30'	System	30 Sep 2020 15:46:19

US3412022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:41:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Sep 2020 15:47:08

US3412022

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	30 Sep 2020 15:47:08

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 64'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-09-29T15:21:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2046ceb1-6bd8-4e46-9113-4c8243df0fcb'	System	29 Sep 2020 19:21:36
User entered 'No (N)'	System	29 Sep 2020 19:21:36

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-09-29T15:21:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2046ceb1-6bd8-4e46-9113-4c8243df0fcb'	System	29 Sep 2020 19:21:36
User entered 'No (N)'	System	29 Sep 2020 19:21:36

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-09-29T15:21:33', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2046ceb1-6bd8-4e46-9113-4c8243df0fcb'	System	29 Sep 2020 19:21:36
User entered '29 Sep 2020 15:21:33'	System	29 Sep 2020 19:21:36

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 71'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-06T16:24:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '256a36e9-113b-47eb-a272-51d9b6603a8e'	System	06 Oct 2020 20:25:21
User entered 'No (N)'	System	06 Oct 2020 20:25:21

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-06T16:24:27', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '256a36e9-113b-47eb-a272-51d9b6603a8e'	System	06 Oct 2020 20:25:21
User entered 'No (N)'	System	06 Oct 2020 20:25:21

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-06T16:24:31', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '256a36e9-113b-47eb-a272-51d9b6603a8e'	System	06 Oct 2020 20:25:21
User entered '06 Oct 2020 16:24:31'	System	06 Oct 2020 20:25:21

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 78'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-12T00:11:05', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0b4828ab-47b9-497e-a8a5-2c900dca92ec'	System	12 Oct 2020 04:11:28
User entered 'No (N)'	System	12 Oct 2020 04:11:28

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-12T00:11:09', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0b4828ab-47b9-497e-a8a5-2c900dca92ec'	System	12 Oct 2020 04:11:28
User entered 'No (N)'	System	12 Oct 2020 04:11:28

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-12T00:11:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '0b4828ab-47b9-497e-a8a5-2c900dca92ec'	System	12 Oct 2020 04:11:28
User entered '12 Oct 2020 00:11:26'	System	12 Oct 2020 04:11:28

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 92'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-26T00:01:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '45604326-ffdb-4bce-99d9-4ed4ff2560d7'	System	26 Oct 2020 04:01:48
User entered 'No (N)'	System	26 Oct 2020 04:01:48

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-26T00:01:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '45604326-ffdb-4bce-99d9-4ed4ff2560d7'	System	26 Oct 2020 04:01:48
User entered 'No (N)'	System	26 Oct 2020 04:01:48

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-10-26T00:01:43', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '45604326-ffdb-4bce-99d9-4ed4ff2560d7'	System	26 Oct 2020 04:01:48
User entered '26 Oct 2020 00:01:43'	System	26 Oct 2020 04:01:48

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 99'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-05T14:36:02', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2509e8c9-72e1-4c86-a80d-e6c6ac66ad2f'	System	05 Nov 2020 19:36:18
User entered 'No (N)'	System	05 Nov 2020 19:36:18

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-05T14:36:11', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2509e8c9-72e1-4c86-a80d-e6c6ac66ad2f'	System	05 Nov 2020 19:36:18
User entered 'No (N)'	System	05 Nov 2020 19:36:18

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-05T14:36:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2509e8c9-72e1-4c86-a80d-e6c6ac66ad2f'	System	05 Nov 2020 19:36:18
User entered '05 Nov 2020 14:36:14'	System	05 Nov 2020 19:36:18

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 106'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:52:44', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered 'Yes (Y)'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:53:05', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered 'Yes (Y)'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:53:10', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:53:15', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered 'No (N)'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:53:20', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered 'No (N)'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-11T13:53:29', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '16d9f996-ab59-4743-82c7-5bdd99627c98'	System	11 Nov 2020 18:53:39
User entered '11 Nov 2020 13:53:29'	System	11 Nov 2020 18:53:39

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:28:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered 'Day 113'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 20:08:33

US3412022

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:52:55
Data entry locked.	System	29 Jul 2020 20:08:33
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 20:08:33

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-20T01:58:08', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5897cab0-c983-41b4-9da6-92f882a70448'	System	20 Nov 2020 06:58:21
User entered 'No (N)'	System	20 Nov 2020 06:58:21

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-20T01:58:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5897cab0-c983-41b4-9da6-92f882a70448'	System	20 Nov 2020 06:58:21
User entered 'No (N)'	System	20 Nov 2020 06:58:21

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-20T01:58:18', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5897cab0-c983-41b4-9da6-92f882a70448'	System	20 Nov 2020 06:58:21
User entered '20 Nov 2020 01:58:18'	System	20 Nov 2020 06:58:21

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-29T20:39:43', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '14e52801-24cd-4d37-88c3-e45a9a1df117'	System	30 Nov 2020 01:39:56
User entered 'No (N)'	System	30 Nov 2020 01:39:56

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-29T20:39:46', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '14e52801-24cd-4d37-88c3-e45a9a1df117'	System	30 Nov 2020 01:39:56
User entered 'No (N)'	System	30 Nov 2020 01:39:56

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (263e96e5eb888dc4)', Time: '2020-11-29T20:39:52', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '14e52801-24cd-4d37-88c3-e45a9a1df117'	System	30 Nov 2020 01:39:56
User entered '29 Nov 2020 20:39:52'	System	30 Nov 2020 01:39:56

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-04T11:39:35', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a61ccdd7-801b-411e-b20d-8acf4ee1a274'	System	04 Dec 2020 16:39:53
User entered 'No (N)'	System	04 Dec 2020 16:39:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-04T11:39:41', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a61ccdd7-801b-411e-b20d-8acf4ee1a274'	System	04 Dec 2020 16:39:53
User entered 'No (N)'	System	04 Dec 2020 16:39:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-04T11:39:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'a61ccdd7-801b-411e-b20d-8acf4ee1a274'	System	04 Dec 2020 16:39:53
User entered '04 Dec 2020 11:39:45'	System	04 Dec 2020 16:39:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-11T02:13:53', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3fbad39c-b488-4a34-916f-75227e628a96'	System	11 Dec 2020 07:14:07
User entered 'No (N)'	System	11 Dec 2020 07:14:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-11T02:13:55', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3fbad39c-b488-4a34-916f-75227e628a96'	System	11 Dec 2020 07:14:07
User entered 'No (N)'	System	11 Dec 2020 07:14:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-11T02:14:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3fbad39c-b488-4a34-916f-75227e628a96'	System	11 Dec 2020 07:14:07
User entered '11 Dec 2020 02:14:01'	System	11 Dec 2020 07:14:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-18T11:15:14', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '547fa59a-2de7-4823-8856-132e2fa7f9b7'	System	18 Dec 2020 16:15:27
User entered 'No (N)'	System	18 Dec 2020 16:15:27

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-18T11:15:18', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '547fa59a-2de7-4823-8856-132e2fa7f9b7'	System	18 Dec 2020 16:15:27
User entered 'No (N)'	System	18 Dec 2020 16:15:27

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-18T11:15:24', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '547fa59a-2de7-4823-8856-132e2fa7f9b7'	System	18 Dec 2020 16:15:27
User entered '18 Dec 2020 11:15:24'	System	18 Dec 2020 16:15:27

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-25T00:20:32', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '81704ff2-187f-4efa-b3eb-7868d31a6ac0'	System	25 Dec 2020 05:20:41
User entered 'No (N)'	System	25 Dec 2020 05:20:41

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-25T00:20:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '81704ff2-187f-4efa-b3eb-7868d31a6ac0'	System	25 Dec 2020 05:20:41
User entered 'No (N)'	System	25 Dec 2020 05:20:41

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2020-12-25T00:20:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '81704ff2-187f-4efa-b3eb-7868d31a6ac0'	System	25 Dec 2020 05:20:41
User entered '25 Dec 2020 00:20:37'	System	25 Dec 2020 05:20:41

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-03T12:15:54', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7cac145d-b0e3-4da2-884a-bf26b03b7d1c'	System	03 Jan 2021 17:16:07
User entered 'No (N)'	System	03 Jan 2021 17:16:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-03T12:15:57', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7cac145d-b0e3-4da2-884a-bf26b03b7d1c'	System	03 Jan 2021 17:16:07
User entered 'No (N)'	System	03 Jan 2021 17:16:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-03T12:16:01', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '7cac145d-b0e3-4da2-884a-bf26b03b7d1c'	System	03 Jan 2021 17:16:07
User entered '03 Jan 2021 12:16:01'	System	03 Jan 2021 17:16:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-08T19:47:27', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a27e21-1d59-4240-aa5d-af3e4842510f'	System	09 Jan 2021 00:47:38
User entered 'No (N)'	System	09 Jan 2021 00:47:38

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-08T19:47:30', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a27e21-1d59-4240-aa5d-af3e4842510f'	System	09 Jan 2021 00:47:38
User entered 'No (N)'	System	09 Jan 2021 00:47:38

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-08T19:47:34', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '54a27e21-1d59-4240-aa5d-af3e4842510f' User entered '08 Jan 2021 19:47:34'	System	09 Jan 2021 00:47:38

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-15T00:30:36', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ada21634-591a-4130-84b2-6ed50c16dcc4'	System	15 Jan 2021 05:30:53
User entered 'No (N)'	System	15 Jan 2021 05:30:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-15T00:30:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ada21634-591a-4130-84b2-6ed50c16dcc4'	System	15 Jan 2021 05:30:53
User entered 'No (N)'	System	15 Jan 2021 05:30:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-15T00:30:49', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ada21634-591a-4130-84b2-6ed50c16dcc4'	System	15 Jan 2021 05:30:53
User entered '15 Jan 2021 00:30:49'	System	15 Jan 2021 05:30:53

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-22T01:17:45', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c19db935-0682-45bd-ad3c-87da8e739b8f'	System	22 Jan 2021 06:18:02
User entered 'No (N)'	System	22 Jan 2021 06:18:02

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-22T01:17:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c19db935-0682-45bd-ad3c-87da8e739b8f'	System	22 Jan 2021 06:18:02
User entered 'No (N)'	System	22 Jan 2021 06:18:02

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-22T01:17:55', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c19db935-0682-45bd-ad3c-87da8e739b8f' User entered '22 Jan 2021 01:17:55'	System	22 Jan 2021 06:18:02

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-30T08:45:23', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e'	System	30 Jan 2021 13:46:17
User entered 'Yes (Y)'	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-30T08:45:26', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e'	System	30 Jan 2021 13:46:17
User entered 'No (N)'	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[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 (e4b6e5c84e18068f)', Time: '2021-01-30T08:45:33', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e'	System	30 Jan 2021 13:46:17
User entered 'No (N)'	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[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 (e4b6e5c84e18068f)', Time: '2021-01-30T08:45:39', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e'	System	30 Jan 2021 13:46:17
User entered 'Yes (Y)'	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-30T08:45:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e'	System	30 Jan 2021 13:46:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-01-30T08:46:04', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9b51784-94ec-4812-940f-8f06a794c70e' User entered '30 Jan 2021 08:46:04'	System	30 Jan 2021 13:46:17
	System	30 Jan 2021 13:46:17

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-12T04:04:37', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3cfac4cb-668a-41b3-8f39-b8aa3401ada8'	System	12 Feb 2021 09:04:49
User entered 'No (N)'	System	12 Feb 2021 09:04:49

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-12T04:04:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3cfac4cb-668a-41b3-8f39-b8aa3401ada8'	System	12 Feb 2021 09:04:49
User entered 'No (N)'	System	12 Feb 2021 09:04:49

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-12T04:04:46', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '3cfac4cb-668a-41b3-8f39-b8aa3401ada8'	System	12 Feb 2021 09:04:49
User entered '12 Feb 2021 04:04:46'	System	12 Feb 2021 09:04:49

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-19T00:02:42', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc59593a-4493-432e-b0df-d912a54ba806'	System	19 Feb 2021 05:03:55
User entered 'No (N)'	System	19 Feb 2021 05:03:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-19T00:02:47', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc59593a-4493-432e-b0df-d912a54ba806'	System	19 Feb 2021 05:03:55
User entered 'No (N)'	System	19 Feb 2021 05:03:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-19T00:02:51', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'fc59593a-4493-432e-b0df-d912a54ba806'	System	19 Feb 2021 05:03:55
User entered '19 Feb 2021 00:02:51'	System	19 Feb 2021 05:03:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-28T23:35:53-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9584ab4-91ea-4830-aff7-c1a0f75f980e'	System	01 Mar 2021 04:36:07
User entered 'No (N)'	System	01 Mar 2021 04:36:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-28T23:35:56-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9584ab4-91ea-4830-aff7-c1a0f75f980e'	System	01 Mar 2021 04:36:07
User entered 'No (N)'	System	01 Mar 2021 04:36:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-28T23:36:00-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'b9584ab4-91ea-4830-aff7-c1a0f75f980e' User entered '28 Feb 2021 23:36:00'	System	01 Mar 2021 04:36:07
	System	01 Mar 2021 04:36:07

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-05T00:40:59-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ad58819f-cc3d-4649-ad2a-bc75e70953c2'	System	05 Mar 2021 05:41:13
User entered 'No (N)'	System	05 Mar 2021 05:41:13

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-05T00:41:03-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ad58819f-cc3d-4649-ad2a-bc75e70953c2'	System	05 Mar 2021 05:41:13
User entered 'No (N)'	System	05 Mar 2021 05:41:13

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-05T00:41:06-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'ad58819f-cc3d-4649-ad2a-bc75e70953c2'	System	05 Mar 2021 05:41:13
User entered '05 Mar 2021 00:41:06'	System	05 Mar 2021 05:41:13

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-12T08:57:56-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2283721c-d48c-44fa-8141-e5047f0055f4'	System	12 Mar 2021 13:58:12
User entered 'No (N)'	System	12 Mar 2021 13:58:12

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-12T08:58:04-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2283721c-d48c-44fa-8141-e5047f0055f4'	System	12 Mar 2021 13:58:12
User entered 'No (N)'	System	12 Mar 2021 13:58:12

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-12T08:58:09-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '2283721c-d48c-44fa-8141-e5047f0055f4'	System	12 Mar 2021 13:58:12
User entered '12 Mar 2021 08:58:09'	System	12 Mar 2021 13:58:12

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-29T23:14:33-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5f900b76-f469-4d4f-b8ac-88d09b0c9ca5'	System	30 Mar 2021 03:14:46
User entered 'No (N)'	System	30 Mar 2021 03:14:46

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-29T23:14:36-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5f900b76-f469-4d4f-b8ac-88d09b0c9ca5'	System	30 Mar 2021 03:14:46
User entered 'No (N)'	System	30 Mar 2021 03:14:46

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-03-29T23:14:39-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '5f900b76-f469-4d4f-b8ac-88d09b0c9ca5'	System	30 Mar 2021 03:14:46
User entered '29 Mar 2021 23:14:39'	System	30 Mar 2021 03:14:46

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-04T19:46:14-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c1d57ed2-9a3b-4fc5-a818-2ad6028415f6'	System	04 Apr 2021 23:46:24
User entered 'No (N)'	System	04 Apr 2021 23:46:24

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-04T19:46:17-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c1d57ed2-9a3b-4fc5-a818-2ad6028415f6'	System	04 Apr 2021 23:46:24
User entered 'No (N)'	System	04 Apr 2021 23:46:24

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-04T19:46:20-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c1d57ed2-9a3b-4fc5-a818-2ad6028415f6'	System	04 Apr 2021 23:46:24
User entered '04 Apr 2021 19:46:20'	System	04 Apr 2021 23:46:24

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-11T08:04:37-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '43346efc-b4e7-46de-a821-129b291f8e97'	System	11 Apr 2021 12:04:48
User entered 'No (N)'	System	11 Apr 2021 12:04:48

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-11T08:04:40-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '43346efc-b4e7-46de-a821-129b291f8e97'	System	11 Apr 2021 12:04:48
User entered 'No (N)'	System	11 Apr 2021 12:04:48

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-11T08:04:44-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '43346efc-b4e7-46de-a821-129b291f8e97'	System	11 Apr 2021 12:04:48
User entered '11 Apr 2021 08:04:44'	System	11 Apr 2021 12:04:48

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-16T00:02:31-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '583c80f6-4d0a-458c-855b-0d3d17a43991'	System	16 Apr 2021 04:03:34
User entered 'No (N)'	System	16 Apr 2021 04:03:34

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-16T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '583c80f6-4d0a-458c-855b-0d3d17a43991'	System	16 Apr 2021 04:03:34
User entered 'No (N)'	System	16 Apr 2021 04:03:34

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-16T00:02:38-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '583c80f6-4d0a-458c-855b-0d3d17a43991'	System	16 Apr 2021 04:03:34
User entered '16 Apr 2021 00:02:38'	System	16 Apr 2021 04:03:34

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-23T11:00:58-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '24d71c69-809b-4744-aae5-8c8ce715c918'	System	23 Apr 2021 15:01:09
User entered 'No (N)'	System	23 Apr 2021 15:01:09

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-23T11:01:02-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '24d71c69-809b-4744-aae5-8c8ce715c918'	System	23 Apr 2021 15:01:09
User entered 'No (N)'	System	23 Apr 2021 15:01:09

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-23T11:01:06-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: '24d71c69-809b-4744-aae5-8c8ce715c918'	System	23 Apr 2021 15:01:09
User entered '23 Apr 2021 11:01:06'	System	23 Apr 2021 15:01:09

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-30T12:51:03-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c297645b-96d0-4d83-8d94-264478a149cb'	System	30 Apr 2021 16:51:16
User entered 'No (N)'	System	30 Apr 2021 16:51:16

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-30T12:51:06-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c297645b-96d0-4d83-8d94-264478a149cb'	System	30 Apr 2021 16:51:16
User entered 'No (N)'	System	30 Apr 2021 16:51:16

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-04-30T12:51:09-04:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c297645b-96d0-4d83-8d94-264478a149cb'	System	30 Apr 2021 16:51:16
User entered '30 Apr 2021 12:51:09'	System	30 Apr 2021 16:51:16

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:52:55

US3412022

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:27:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:52:55
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:52:55

US3412022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-28T23:35:44-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c4e5968f-0b65-4a03-a9e4-3878112ee901'	System	01 Mar 2021 04:35:52
User entered 'No (N)'	System	01 Mar 2021 04:35:52

US3412022

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:27:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4b6e5c84e18068f)', Time: '2021-02-28T23:35:47-05:00', User OID: 'PatientReportedOutcome (US3412022)', ODM File OID: 'c4e5968f-0b65-4a03-a9e4-3878112ee901' User entered '28 Feb 2021 23:35:47'	System	01 Mar 2021 04:35:52
	System	01 Mar 2021 04:35:52

US3412022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Oct 2020 14:38:46

US3412022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered '21 Oct 2020'	Mason Urban (b) (4)	21 Oct 2020 14:38:46

US3412022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Oct 2020 14:38:46

US3412022

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered empty.	Mason Urban (b) (4)	21 Oct 2020 14:38:46

US3412022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Oct 2020 14:38:51

US3412022

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:13:24
User entered 'I'	System	21 Oct 2020 14:38:51

US3412022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'No (N)'	Mason Urban (b) (4)	19 Feb 2021 18:11:13

US3412022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:11:13

US3412022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:11:13

US3412022

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'PATIENT NOT CONTACTED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE SAFETY CALLS ALONGSIDE ILLNESS VISITS'	Mason Urban (b) (4)	19 Feb 2021 18:11:13

US3412022

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:32:05

US3412022

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'I'	System	29 Dec 2020 21:32:05

US3412022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:32:15

US3412022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
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)	06 Jan 2021 19:47:09
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 'CALLED AND LEFT VOICEMAILS 23 DEC 2020 AND 28 DEC 2020. WAS ABLE TO REACH 29 DEC 2020' (Site from System).	Mason Urban (b) (4) (b) (4)	29 Dec 2020 21:33:13
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	29 Dec 2020 21:32:15
User entered '29 Dec 2020'	Mason Urban (b) (4) (b) (4)	29 Dec 2020 21:32:15

US3412022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	29 Dec 2020 21:32:15

US3412022

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	29 Dec 2020 21:32:15

US3412022

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	29 Dec 2020 21:33:18

US3412022

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'I'	System	29 Dec 2020 21:33:18

US3412022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'No (N)'	Mason Urban (b) (4)	19 Feb 2021 18:10:50

US3412022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:10:50

US3412022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 18:10:50

US3412022

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'PATIENT NOT CONTACTED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE SAFETY CALLS ALONGSIDE OPEN LABEL PHASE'	Mason Urban (b) (4)	19 Feb 2021 18:10:50

US3412022

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Feb 2021 18:10:54

US3412022

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'I'	System	19 Feb 2021 18:10:54

US3412022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:04:11

US3412022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:04:11

US3412022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Mar 2021 17:04:11

US3412022

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'VISIT4'	System	31 Mar 2021 17:04:11

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '15:20'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered '25 Feb 2021 15:20'	System	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '98.0' F	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '69'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'bpm'	System	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '16'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'breaths/min'	System	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '122'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'mmHg'	System	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '74'	Steven Anderson (b) (4)	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'mmHg'	System	31 Mar 2021 17:04:55

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09

US3412022

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09

US3412022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:05:04

US3412022

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:05:04

US3412022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:05:48

US3412022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:05:48

US3412022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '13:38'	Steven Anderson (b) (4)	31 Mar 2021 17:05:48

US3412022

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered '25 Feb 2021 13:38'	System	31 Mar 2021 17:05:48

US3412022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Mar 2021 14:00:46

US3412022

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:47:09
User entered 'I'	System	23 Mar 2021 14:00:46

US3412022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Mar 2021 14:01:45

US3412022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '23 Mar 2021'	Mason Urban (b) (4)	23 Mar 2021 14:01:45

US3412022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Mar 2021 14:01:45

US3412022

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Mason Urban (b) (4)	23 Mar 2021 14:01:45

US3412022

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Mar 2021 14:01:48

US3412022

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:03
User entered 'I'	System	23 Mar 2021 14:01:48

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:27:38
User closed query 'Please reconcile and enter severity page' (Site from CRA).	(b) (4)	18 Nov 2020 18:24:48
Query 'Please reconcile and enter severity page' answered with 'UPDATED SEVERITY PAGE' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 21:41:23
User opened query 'Please reconcile and enter severity page' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:29:50
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:00:17

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:34:34
User closed query 'please confirm time' (Site from CRA).	(b) (4)	24 Nov 2020 01:34:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 13:53:49
Query 'Data is required. Please complete.' answered with 'time was not documented by site' (Site from System).	Steven Anderson (b) (4)	19 Nov 2020 19:50:05
Query 'please confirm time' answered with 'time was not documented by site' (Site from CRA).	(b) (4)	19 Nov 2020 19:50:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 19:49:50
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:49:50
User opened query 'please confirm time' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:27:57
User entered '11:15'	(b) (4)	12 Nov 2020 18:00:17

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:03
User entered empty.	System	19 Nov 2020 19:49:50
User entered '12 Nov 2020 11:15'	System	12 Nov 2020 18:00:17

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:27:41
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'		12 Nov 2020 18:00:17

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:03
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:27:43
User entered 'Yes (Y)'		12 Nov 2020 18:00:17

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
Query 'Per source note on 12 Nov 2020, symptoms started on 07 Nov 2020 with mild congestion, cough and fever = 99.8 F - please update symptom log to include 07 Nov 2020 as Day 1' canceled (Site from CRA).		18 Nov 2020 18:38:09
User opened query 'Per source note on 12 Nov 2020, symptoms started on 07 Nov 2020 with mild congestion, cough and fever = 99.8 F - please update symptom log to include 07 Nov 2020 as Day 1' (Site from CRA).		18 Nov 2020 18:34:38
User closed query 'Please reconcile as AE start date = 07Nov2020 and per CCGs first date of symptoms = day 1 on symptom log' (Site from CRA).		18 Nov 2020 18:34:38
User entered '08 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 21:37:33
Query 'Please reconcile as AE start date = 07Nov2020 and per CCGs first date of symptoms = day 1 on symptom log' answered with 'RECONCILED WITH AE START DATE' (Site from CRA).	(b) (4) Melissa Fuson (b) (4)	17 Nov 2020 21:36:25
User entered '07 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 21:35:58
User opened query 'Please reconcile as AE start date = 07Nov2020 and per CCGs first date of symptoms = day 1 on symptom log' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:31:29
User entered '08 Nov 2020'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:38:23
DataPoint Un-verified.	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	19 Nov 2020 19:52:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '1'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 19:54:27
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 2, 3, 4, 5, 6, 28 and Temperature for Days 2, 3, 4. If not collected, please consider recording these as NOT DONE' (Site from DM).		12 Jan 2021 09:30:08
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 2, 3, 4, 5, 6, 28 and Temperature for Days 2, 3, 4. If not collected, please consider recording these as NOT DONE' answered with 'UPDATED TO NOT DONE ' (Site from DM).	Melissa Fuson (b) (4)	11 Jan 2021 20:58:33
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:57:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	11 Jan 2021 20:57:22
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 2, 3, 4, 5, 6, 28 and Temperature for Days 2, 3, 4. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:49:08
DataPoint Verified.		18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	11 Jan 2021 20:57:22
User entered empty.	System	12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:28
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:58:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 20:58:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:05:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 2 (Day 2)'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:06:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '09 Nov 2020'		12 Nov 2020 18:06:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:38:28
DataPoint Un-verified.	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	19 Nov 2020 19:52:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '1'		12 Nov 2020 18:06:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:33
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:58:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 20:58:56
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:06:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	11 Jan 2021 20:58:56
User entered empty.	System	12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:35
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:58:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 20:58:56
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:06:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 3 (Day 3)'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:07:22

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '10 Nov 2020'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:38:32
DataPoint Un-verified.	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	19 Nov 2020 19:52:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '1'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:40
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:59:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 20:59:13
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:07:22

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	11 Jan 2021 20:59:13
User entered empty.	System	12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:42
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:59:13
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	11 Jan 2021 20:59:13
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:07:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 4 (Day 4)'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '11 Nov 2020'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:57:13
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:54:48
DataPoint Un-verified.	Melissa Fuson (b) (4)	11 Jan 2021 20:59:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	11 Jan 2021 20:59:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:08:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	11 Jan 2021 20:59:25
User entered empty.	System	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '99.8' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:57:13
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:57:30
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:57:13
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:08:05

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 5 (Day 5)'	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 18:38:30

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 19:54:54
User closed query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done.' (Site from DM).		18 Jan 2021 10:09:15
Query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done.' answered with 'O2 SATURATION WAS NOT DONE - UPDATED.' (Site from DM).	Melissa Fuson (b) (4)	12 Jan 2021 16:17:53
DataPoint Un-verified.	(b) (4)	12 Jan 2021 16:17:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	12 Jan 2021 16:17:25
User opened query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:34:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered empty.		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	12 Jan 2021 16:17:25
User entered empty.	System	12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '37.1' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 13:49:08
User entered '97.1' C	(b) (4) (b) (4), (b) (6)	12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		12 Nov 2020 18:38:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 6 (Day 6)'	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 17:49:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 17:49:25

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '97.5' F		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:44:59
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'		13 Nov 2020 17:49:25

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 7 (Day 7)'	Melissa Fuson (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '14 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '97'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98.1' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:05:01

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 8 (Day 8)'	(b) (4)	
	Melissa Fuson (b) (4)	17 Nov 2020 14:07:27
	(b) (4)	

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '15 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98.1' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:07:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 9 (Day 9)'	(b) (4)	
	Melissa Fuson (b) (4)	17 Nov 2020 14:12:29
	(b) (4)	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '16 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '97.9' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 14:12:29

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Steven Anderson (b) (4)	19 Nov 2020 19:52:50
User entered 'Day 10 (Day 10)'	(b) (4)	
	Melissa Fuson (b) (4)	18 Nov 2020 13:17:40
	(b) (4)	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '17 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '0'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '98'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered '97.9' F	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:44:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 13:17:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 1 (Day 1)'	Steven Anderson (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered '07 Nov 2020'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered '0'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
Query 'please enter Not Done' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:18:18
DataPoint Verified.		24 Nov 2020 22:18:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 22:17:17
User opened query 'please enter Not Done' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:09:35
DataPoint Un-verified.		24 Nov 2020 22:09:20
DataPoint Verified.		24 Nov 2020 22:07:48
User entered empty.	Steven Anderson (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	24 Nov 2020 22:17:17
User entered empty.	System	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
Query 'please enter Not Done' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:18:19
DataPoint Verified.		24 Nov 2020 22:18:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 22:17:17
User opened query 'please enter Not Done' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 22:09:43
DataPoint Un-verified.		24 Nov 2020 22:09:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered empty.	Steven Anderson (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'Mild (Mild)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'Mild (Mild)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Steven Anderson (b) (4) (b) (4)	19 Nov 2020 19:51:31

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 12 (Day 12)' reason for change:	Melissa Fuson (b) (4)	20 Nov 2020 13:26:28
Data Entry Error	(b) (4)	
User entered 'Day 18 (Day 18)'	Melissa Fuson (b) (4)	20 Nov 2020 13:17:19
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:15
User entered '18 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:16
User entered '0'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:12
User entered '99'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 13:21:23
User entered '97.9' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:21:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Nov 2020 13:17:19
User entered '97.9' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:27
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:06:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:17:19

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:37
User entered '19 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:38
User entered '0'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:40
User entered '98'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered '98.1' F	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:07:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	20 Nov 2020 13:31:38

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 14 (Day 14)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:49:59
User entered '20 Nov 2020'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:01
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:10
User entered '98'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:11
User entered '96.4' F	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:48
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:50
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:52
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:53
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:55
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:57
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:50:59
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:00
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:02
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:04
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:06
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:08
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:10
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:12
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:14
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:16
User entered 'Mild (Mild)'	Steven Anderson (b) (4)	23 Nov 2020 18:36:46

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 15 (Day 15)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:37
User entered '21 Nov 2020'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:39
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:45
User entered '99'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:51:47
User entered '98.6' F	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:08
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:09
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:11
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:12
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:14
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:16
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:17
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:19
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:21
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:22
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:24
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:25
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:27
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:29
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:30
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:52:32
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:37:39

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 16 (Day 16)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:53:21
User entered '22 Nov 2020'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:53:23
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User closed query '98% per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:23:01
DataPoint Verified.		24 Nov 2020 21:22:59
Query '98% per source. Please confirm and update as appropriate' answered with 'this has been updated.' (Site from CRA).	Steven Anderson (b) (4)	24 Nov 2020 21:01:13
User entered '98' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 21:01:05
User opened query '98% per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:53:53
DataPoint Un-verified.		24 Nov 2020 18:53:40
DataPoint Verified.		24 Nov 2020 18:53:30
User entered '99'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:36
User entered '98.1' F	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:38
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:39
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:41
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:43
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:45
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:46
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:49
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:52
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:54
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:55
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:54:57
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:19
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:21
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:24
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:25
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:03:26
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:38:28

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 17 (Day 17)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:26
User entered '23 Nov 2020'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:28
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:40
User entered '98'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:41
User entered '97.4' F	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:47
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:49
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:52
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:54
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:55
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:57
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:04:58
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:00
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:02
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:03
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:05
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:06
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:05:08
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:13:35
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:13:36
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 19:13:45
User entered 'None (None)'	Steven Anderson (b) (4)	23 Nov 2020 18:39:22

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 18 (Day 18)'	Melissa Fuson (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:14
User entered '24 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:19
User entered '0'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:21
User entered '99'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:27
User entered '97.8' F	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:36
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:53
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:58:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:55:00

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 19 (Day 19)'	Melissa Fuson (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:45
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:48
User entered '0'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:51
User entered '98'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User entered '%'	System	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:52
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:58
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:59:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:00:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:00:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:00:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:00:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:00:08
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:12
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:14
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:16
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:01:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	25 Nov 2020 20:57:27

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 28 (Day 28)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	08 Dec 2020 14:05:22
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	08 Dec 2020 14:04:40
	(b) (4)	

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:02:18
User entered '4 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:02:20
User entered '0'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
Query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done. ' canceled (Site from DM).		26 Apr 2021 14:05:10
User opened query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done. ' (Site from DM).		26 Apr 2021 13:41:09
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:44:21
User closed query 'please update to Not Done' (Site from CRA).		11 Mar 2021 00:44:18
Query 'please update to Not Done' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	25 Feb 2021 17:25:52
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Feb 2021 17:25:47
User opened query 'please update to Not Done' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 18:25:37
User closed query 'Please confirm Not done and update accordingly' (Site from CRA).		18 Feb 2021 18:25:37
Query 'Please confirm Not done and update accordingly' answered with 'not done' (Site from CRA).	Andrea Newlands (b) (4)	18 Feb 2021 17:30:52
User opened query 'Please confirm Not done and update accordingly' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 02:03:04
DataPoint Un-verified.		11 Feb 2021 02:02:31
DataPoint Verified.		30 Dec 2020 14:02:22
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
Query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done.' canceled (Site from DM).		26 Apr 2021 13:41:02
User entered '%'	System	25 Feb 2021 17:25:47
User opened query 'Per CDM: O2 Saturation is blank, if it was not collected please record as Not Done.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:36:06
User entered empty.	System	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User closed query '36.8 C per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 19:56:20
DataPoint Verified.		26 Jan 2021 19:56:18
Query '36.8 C per source. Please confirm and update as appropriate' answered with 'updated per source' (Site from CRA).	Melissa Fuson (b) (4)	30 Dec 2020 21:31:18
User entered '36.8' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 21:31:04
User opened query '36.8 C per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	30 Dec 2020 14:02:45
User entered '36.5' C	Melissa Fuson (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:23
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:27
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:54
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:03:57
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:04:40

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered '12 Nov 2020'		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered 'Yes (Y)'		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
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)	23 Nov 2020 13:52:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
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 'COVID 19 test came back positive ' (Site from System).	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:49:59
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 16:49:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 16:49:30
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	16 Nov 2020 16:49:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:49:30
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 18:00:44
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered '12 Nov 2020'		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered empty.		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered 'No (N)'		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered empty.		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:54:49
User entered empty.		12 Nov 2020 18:00:44

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:19
User entered 'I'	System	16 Nov 2020 16:49:30

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:08:01
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:08:01
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:08:01
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:08:01
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:07:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:07:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:07:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:07:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User closed query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 18:19:07
Query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' answered with 'updated both to NO' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 20:24:07
User opened query 'Per CDM: Please review both Evidence of Shock and Evidence of Pneumonia sections of this form and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 22:12:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:08:01
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:56:43
DataPoint Un-verified.	Melissa Fuson (b) (4)	06 Jan 2021 20:23:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	06 Jan 2021 20:23:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 16:07:16

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:28:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:28:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:28:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 16:07:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

US3412022

Folder: Covid-19 Assessment 12 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:27:21

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:07:16

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:27:21

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:29
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:55:14
User entered 'No (N)'		12 Nov 2020 18:00:51

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:35
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:13
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:10:33

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:35
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:13
User entered '11:20'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:10:33

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:35
User entered '23 Dec 2020 11:20'	System	23 Dec 2020 18:10:33

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:35
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:13
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:10:33

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:27:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:35
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:15:49
User closed query 'Please confirm if subject was reporting symptoms. No symptoms per source' (Site from CRA).	(b) (4)	18 Feb 2021 18:15:46
Query 'Please confirm if subject was reporting symptoms. No symptoms per source' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	18 Feb 2021 17:35:56
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 17:35:52
User opened query 'Please confirm if subject was reporting symptoms. No symptoms per source' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 18:41:30
DataPoint Un-verified.	(b) (4)	27 Jan 2021 18:41:15
DataPoint Verified.	(b) (4)	27 Jan 2021 18:41:13
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	23 Dec 2020 18:10:33

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	23 Dec 2020 18:14:15
User entered empty.	System	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered '98.0' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:37:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 18:14:15
User entered empty.	Melissa Fuson (b) (4)	23 Dec 2020 18:11:36

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 2 (Day 2)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered '24 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered '98'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered '98.1' F	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:14
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:14:52

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 3 (Day 3)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered '25 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered '98'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered '98.9' F	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:27
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:15:39

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 4 (Day 4)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered '26 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered '98'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered '98.5' F	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:40
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:16:34

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 5 (Day 5)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered '27 Dec 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	25 Jan 2021 22:18:12
User entered '27 Nov 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered '98'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered '98.2' F	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:38:56
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:17:20

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 6 (Day 6)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered '28 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered '98'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered '98.0' F	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:39:04
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:18:12

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 7 (Day 7)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered '29 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered '98'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:19:05

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Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered '97.8' F	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:00
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:19:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 8 (Day 8)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered '30 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered '0'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered '99'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered '97.2' F	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:15
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:05

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Day 9 (Day 9)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered '31 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered '0'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered '98'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User entered '%'	System	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered '97.7' F	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:27:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:40:45
User entered 'None (None)'	Steven Anderson (b) (4)	25 Jan 2021 22:20:53

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 20:21:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 20:21:59
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 20:21:59
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 18:14:35
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:36:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:14:35

US3412022

Folder: Covid-19 Assessment 23 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:27:21

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:25:45
User entered '0'	System	06 Jan 2021 20:21:59

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:08:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 04:59:57
Query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you' answered with 'will be updated with pppd' (Site from DM).	Andrea Newlands (b) (4)	12 Apr 2021 13:11:13
User opened query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 03:37:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 14:09:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:16:46

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 18:59:44
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:00
User entered '14 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:09:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:09:26
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 10:16:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 18:59:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:10
User entered '16 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:09:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 14:09:36
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		18 Dec 2020 10:17:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4)	17 Dec 2020 19:00:11
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:21
User entered '18 Nov 2020'	Melissa Fuson (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:09:43
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 14:09:44
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		18 Dec 2020 10:17:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:00:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20NOV2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:29
User entered '20 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:10:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 14:10:14
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		18 Dec 2020 10:17:14
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 19:00:41
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:37
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:10:49
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 14:10:50
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		18 Dec 2020 10:17:20
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'PER SOURCE DOCUMENT SALIVA DAYS 3,5,7,9,14 & 21 WERE SENT ON 04-DEC-2020 AND PER ACCESSION NUMBER: 1F60353 DAYS 5,7,9,21, WERE ONLY ONES REPORTED.' (Site from DM).	Melissa Fuson (b) (4)	17 Dec 2020 19:01:03
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 02DEC2020 is recorded under Illness Visit Day 21 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:41:45
User entered '02 Dec 2020'	Melissa Fuson (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:19:19
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Dec 2020 19:20:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Dec 2020 19:20:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 19:20:45
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:07:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:19:21
User entered '4 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 19:20:45
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 21:07:29

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User closed query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 03:36:21
Query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' answered with 'this is on the incorrect illness visit line as this is illness visit 2 illness visit 1 dates have been updated to the appropriate dates marked on edc. Site has also changed preclarus' (Site from DM).	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 19:05:52
User opened query 'Per GCL Lab Recon: Saliva: Per Preclarus report, there seems to be a data entry error in 'PPD GCL' records for this "Day 3,5, 7,9, 14, 21 & 28" Saliva samples collection dates as all are recorded as collected on a single day only, i.e on "04 DEC 2020", which seems to be a Data entry error. Please kindly send a DCF to PPD GCL to update the correct sample collection dates in Preclarus PPD portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 18:16:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25DEC2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).		21 Feb 2021 18:14:12

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25DEC2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 05:17:44
		27 Jan 2021 18:50:53
User entered '25 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered '27 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered '29 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'Yes (Y)'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered '31 Dec 2020'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'NA (COVID-19 Negative) (NA)'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered empty.	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'NA (COVID-19 Negative) (NA)'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered empty.	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Steven Anderson (b) (4) (b) (4)	25 Jan 2021 22:12:13

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered 'NA (COVID-19 Negative) (NA)'	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:50:53
User entered empty.	Steven Anderson (b) (4)	25 Jan 2021 22:12:13
	(b) (4)	

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User closed query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 15:26:12
Query 'Please reconcile and enter saliva log' answered with 'SALIVA LOG ENTERED AND UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 13:55:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:09
User opened query 'Please reconcile and enter saliva log' (Site from CRA).		17 Nov 2020 15:30:41
User entered 'Yes (Y)'		12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:09
User entered '12 Nov 2020'		12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:09
User entered 'Clinic (Clinic)'		12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'SICKD1'	System	12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered 'Yes (Y)'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '12 Nov 2020'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:39:41
User entered '11:35'	(b) (4), (b) (6)	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered '12 Nov 2020 11:35'	System	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '186.5' cm		12 Nov 2020 18:39:46
DataPoint set to visible.	System	12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '152.9' kg		12 Nov 2020 18:39:46
DataPoint set to visible.	System	12 Nov 2020 18:38:56

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '37.1' C		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered 'Oral (Oral)'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '82'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'bpm'	System	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4)	18 Nov 2020 18:39:41
User entered '19'	(b) (4), (b) (6)	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'breaths/min'	System	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '124'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'mmHg'	System	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:41
User entered '66'		12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'mmHg'	System	12 Nov 2020 18:39:46

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:47
User entered 'Yes (Y)'		12 Nov 2020 18:39:55

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:47
User entered '12 Nov 2020'		12 Nov 2020 18:39:55

US3412022

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:39:58
User entered 'Yes (Y)'		12 Nov 2020 18:40:06

US3412022

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:39:58
User entered '12 Nov 2020'		12 Nov 2020 18:40:06

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:50
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:50
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:41:50
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'SICKD1'	System	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '23 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:30:18
User closed query '11:30 per source? Please confirm and update accordingly' (Site from CRA).		18 Feb 2021 18:30:16
Query '11:30 per source? Please confirm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	18 Feb 2021 17:46:31
User entered '11:30' reason for change: Data Entry Error	Andrea Newlands (b) (4)	18 Feb 2021 17:46:26
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 18:43:18
DataPoint Verified.		27 Jan 2021 18:43:15
User opened query '11:30 per source? Please confirm and update accordingly' (Site from CRA).		27 Jan 2021 18:42:30
User entered '11:20'	Melissa Fuson (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered '23 Dec 2020 11:30'	System	18 Feb 2021 17:46:26
User entered '23 Dec 2020 11:20'	System	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '186.5' cm	Melissa Fuson (b) (4)	23 Dec 2020 18:09:35
DataPoint set to visible.	(b) (4) System	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '157.8' kg	Melissa Fuson (b) (4)	23 Dec 2020 18:09:35
DataPoint set to visible.	(b) (4) System	23 Dec 2020 18:08:15

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '98.0' F	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '60'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'bpm'	System	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '16'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'breaths/min'	System	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '110'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'mmHg'	System	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:43:15
User entered '70'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User entered 'mmHg'	System	23 Dec 2020 18:09:35

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23

US3412022

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:44:15
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:50

US3412022

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:44:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:09:50

US3412022

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:44:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 18:10:03

US3412022

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:44:28
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).		18 Jan 2021 13:00:49
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 'SAMPLE HAS BEEN SHIPPED WITH ACCESSION NUMBER 1F60353' (Site from DM).	Melissa Fuson (b) (4)	06 Jan 2021 20:25:04
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 06:50:21
User entered '23 Dec 2020'	Melissa Fuson (b) (4)	23 Dec 2020 18:10:03

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:04:41
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 13:58:51

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:04:41
User entered '4 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 13:58:51

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:04:41
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 13:58:51

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered 'SICKD28'	System	08 Dec 2020 13:58:51

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '4 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '11:15'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered '4 Dec 2020 11:15'	System	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:55:12
User closed query '36.8 C per source. Please confirm and update as appropriate' (Site from CRA).		04 Feb 2021 23:53:25
Query '36.8 C per source. Please confirm and update as appropriate' answered with 'updated per source' (Site from CRA).	Melissa Fuson (b) (4)	30 Dec 2020 21:32:02
User entered '36.8' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 21:31:54
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 14:06:58
DataPoint Verified.		30 Dec 2020 14:06:55
User opened query '36.8 C per source. Please confirm and update as appropriate' (Site from CRA).		30 Dec 2020 14:06:24
User entered '36.5' C	Melissa Fuson (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered empty.	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '68'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered 'bpm'	System	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '18'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered 'breaths/min'	System	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '128'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered 'mmHg'	System	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:06:55
User entered '70'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User entered 'mmHg'	System	08 Dec 2020 14:00:15

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:07:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:34

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:07:11
User entered '4 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:00:34

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 14:07:20
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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).		14 Dec 2020 11:23:38
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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 'the date has been updated to correct date of 04-Dec-2020' (Site from DM).	Steven Anderson (b) (4)	11 Dec 2020 15:38:33
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 04 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum 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)	10 Dec 2020 10:07:07
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Dec 2020 14:00:48

US3412022

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:27:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:07:20
User entered '04 Dec 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Dec 2020 15:38:11
User entered '7 Dec 2020'	Melissa Fuson (b) (4)	08 Dec 2020 14:00:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:19

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:19

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:19

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 23:48:19

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021'	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 17:56:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:47:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 08:41:08
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 17:56:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 17:56:11
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:40:34
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:47:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:07:25
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:07:25
User entered 'Placebo (Placebo)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:48:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '1'	System	06 Jan 2021 23:48:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:27:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '183.5' cm	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '157.0' kg	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '46.62593'	System	06 Jan 2021 23:52:44
DataPoint set to visible.	System	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '183.5' cm	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '157.0' kg	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '46.62593'	System	06 Jan 2021 23:52:44
DataPoint set to visible.	System	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
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	06 Jan 2021 23:53:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:53:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 23:52:44
	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:03
User entered '15:07' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '6 Jan 2021 15:07'	System	06 Jan 2021 23:54:03
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:03
User entered '37.1' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:28
Query 'Data is required. Please provide.' answered by System	System	06 Jan 2021 23:54:28
data change (Site from System).		06 Jan 2021 23:54:28
User entered 'Oral (Oral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:03
User entered empty.	System	06 Jan 2021 23:52:44
	Melissa Fuson (b) (4)	
	(b) (4)	

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:03
User entered '72' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:03
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	06 Jan 2021 23:54:03
User entered empty.	System	06 Jan 2021 23:52:44

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:28
User entered '14' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	06 Jan 2021 23:54:28
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:28
User entered '140' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	06 Jan 2021 23:54:28
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:54:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:54:28
User entered '90' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:54:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	06 Jan 2021 23:54:28
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '183.5' cm	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '157.0' kg	(b) (4) Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:27:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '46.62593'	System	06 Jan 2021 23:52:44
DataPoint set to visible.	System	06 Jan 2021 23:48:48

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
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	06 Jan 2021 23:53:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:53:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Jan 2021 23:52:44
	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '15:58' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	System	06 Jan 2021 23:52:44
	Melissa Fuson (b) (4)	
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '6 Jan 2021 15:58'	System	06 Jan 2021 23:55:55
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '37.2' C reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '74' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	06 Jan 2021 23:55:55
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '15' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	06 Jan 2021 23:55:55
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '148' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	06 Jan 2021 23:55:55
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:55:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Jan 2021 23:55:55
User entered '88' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 23:55:55
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Jan 2021 23:53:26
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:52:44
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	06 Jan 2021 23:55:55
User entered empty.	System	06 Jan 2021 23:52:44

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:06

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:06

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 23:56:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mRNA-1273'	System	06 Jan 2021 23:56:27
DataPoint set to visible.	System	06 Jan 2021 23:48:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:27

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '15:22'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '6 Jan 2021 15:22'	System	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Left Arm (LEFT ARM)'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'ONCE'	System	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 23:56:27

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:54

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:54

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '15:33'	Melissa Fuson (b) (4)	06 Jan 2021 23:56:54

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '6 Jan 2021 15:33'	System	06 Jan 2021 23:56:54

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:57:09

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '6 Jan 2021'	Melissa Fuson (b) (4)	06 Jan 2021 23:57:09

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '15:14'	Melissa Fuson (b) (4)	06 Jan 2021 23:57:09

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:27:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '6 Jan 2021 15:14'	System	06 Jan 2021 23:57:09

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 23:57:16

US3412022

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	06 Jan 2021 23:57:16

US3412022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 18:53:14

US3412022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered '13 Jan 2021'	Mason Urban (b) (4)	13 Jan 2021 18:53:14

US3412022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	13 Jan 2021 18:53:14

US3412022

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered empty.	Mason Urban (b) (4)	13 Jan 2021 18:53:14

US3412022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	13 Jan 2021 18:53:18

US3412022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	13 Jan 2021 18:53:18

US3412022

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '1'	System	13 Jan 2021 18:53:18
DataPoint set to visible.	System	13 Jan 2021 18:53:18

US3412022

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User closed query 'Please complete visit CRFs' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:19:40
Query 'Please complete visit CRFs' answered with 'these have been completed' (Site from CRA).	Steven Anderson (b) (4)	09 Apr 2021 19:18:22
User opened query 'Please complete visit CRFs' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 13:21:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 21:09:46

US3412022

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User closed query 'Per CDM re-query: Site response noted. However the visit date is 50 days after Participant decision visit which is outside of the allowed window. Please clarify why the visit performed out of window in query response. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:01:48
Query 'Per CDM re-query: Site response noted. However the visit date is 50 days after Participant decision visit which is outside of the allowed window. Please clarify why the visit performed out of window in query response. Thank you ' answered with 'This is correct. Due to subject having medical issues PI determined subject needed to hold second dose until medically stable. PI then determined subject was eligible for second injection' (Site from DM).	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 19:21:12
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 10:43:14
User opened query 'Per CDM re-query: Site response noted. However the visit date is 50 days after Participant decision visit which is outside of the allowed window. Please clarify why the visit performed out of window in query response. Thank you ' (Site from DM).		04 Mar 2021 10:43:12
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'dates correct' (Site from System).	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:25:15
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	25 Feb 2021 21:09:46
User entered '25 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:09:46

US3412022

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	25 Feb 2021 21:09:46

US3412022

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'OLD29'	System	25 Feb 2021 21:09:46

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49
	(b) (4)	

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '13:42'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '25 Feb 2021 13:42'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '37.1' C	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '74'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '16'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '135'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '82'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '15:20'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '25 Feb 2021 15:20'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '98.0' F	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '69'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '16'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '122'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '74'	Steven Anderson (b) (4)	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	31 Mar 2021 17:01:49

US3412022

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:02:12

US3412022

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:02:12

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mRNA-1273'	System	31 Mar 2021 17:02:35
DataPoint set to visible.	System	13 Jan 2021 18:53:18

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '14:45'	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '25 Feb 2021 14:45'	System	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'ONCE'	System	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:27:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'INTRAMUSCULAR'	System	31 Mar 2021 17:02:35

US3412022

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 17:25:39

US3412022

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	04 Mar 2021 17:25:39

US3412022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 17:26:42

US3412022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered '4 Mar 2021'	Mason Urban (b) (4)	04 Mar 2021 17:26:42

US3412022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Mar 2021 17:26:42

US3412022

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:27:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered empty.	Mason Urban (b) (4)	04 Mar 2021 17:26:42

US3412022

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:22
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 17:26:51

US3412022

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:27:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'I'	System	04 Mar 2021 17:26:51

US3412022

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:12:56

US3412022

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:12:56

US3412022

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:12:56

US3412022

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:27:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'OLD57'	System	25 Mar 2021 18:12:56

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '13:22'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '25 Mar 2021 13:22'	System	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '62'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'bpm'	System	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '12'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'breaths/min'	System	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '132'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '62'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered 'mmHg'	System	25 Mar 2021 18:13:51

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26

US3412022

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:27:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26

US3412022

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:02

US3412022

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:27:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:02

US3412022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:55

US3412022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:55

US3412022

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered '13:25'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 18:14:55

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:27:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:51:26
User entered '25 Mar 2021 13:25'	System	25 Mar 2021 18:14:55

US3412022

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:27:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:38:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:50:20
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	14 Sep 2020 12:58:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	18 Nov 2020 18:28:42
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:29
User entered	System	17 Nov 2020 16:47:23
'USA-US061-2020-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 16:47:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 18:55:51
User closed query 'Per CRF completion guidelines version 4 dated 28 Dec 2020 page 67, please enter AE term as " Symptomatic Covid-19 " (without quotation marks)' (Site from CRA).		27 Jan 2021 18:55:49
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)	27 Jan 2021 13:40:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:40:14
Query 'Per CRF completion guidelines version 4 dated 28 Dec 2020 page 67, please enter AE term as " Symptomatic Covid-19 " (without quotation marks)' answered with 'term has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 13:38:52
Data point term sent to Coder	System	27 Jan 2021 13:38:41
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 13:38:22
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 13:38:22
User opened query 'Per CRF completion guidelines version 4 dated 28 Dec 2020 page 67, please enter AE term as " Symptomatic Covid-19 " (without quotation marks)' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:01:26
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)	08 Dec 2020 14:19:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Dec 2020 14:19:58
Data point term sent to Coder	System	08 Dec 2020 14:19:19
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:18:43
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:18:43
User entered 'COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:18:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Please update term to Symptomatic COVID-19 per eCRF guidelines' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:22:31
		24 Nov 2020 21:22:27
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)	24 Nov 2020 20:11:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:11:00
Data point term sent to Coder	System	24 Nov 2020 20:10:15
Query 'Please update term to Symptomatic COVID-19 per eCRF guidelines' answered with 'this is updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:09:20
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:09:13
User opened query 'Please update term to Symptomatic COVID-19 per eCRF guidelines' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:45:50
		24 Nov 2020 18:45:08
DataPoint Verified.		24 Nov 2020 02:09:06
User entered 'COVID-19' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 19:10:06
Data point term sent to Coder	System	23 Nov 2020 16:54:08
User entered 'Suspicious COVID-19' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:53:14
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System).	System	23 Nov 2020 16:21:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' answered with 'subject confirmed to have COVID-19 info has been updated' (Site from System). DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:21:28
Coding entries removed.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:21:00
User entered 'COVID-19' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:21:00
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4), (b) (6)	23 Nov 2020 12:24:35 18 Nov 2020 18:28:41
User closed query 'Please update to Symptomatic COVID-19' (Site from CRA).	(b) (4)	18 Nov 2020 18:28:27
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:55:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:55:50
Query 'Please update to Symptomatic COVID-19' answered with 'UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:40:54
Data point term sent to Coder	System	17 Nov 2020 21:39:51
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:39:20
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:39:20
User opened query 'Please update to Symptomatic COVID-19' (Site from CRA).	(b) (4), (b) (6) (b) (4)	17 Nov 2020 19:58:00
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:24:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 16:24:48
Data point term sent to Coder	(b) (4)	
User closed query 'For coding purposes, for term COVID-19 (LIKE SYMPTOMS), please enter symptoms. One per line' (Site from System).	System	17 Nov 2020 16:23:12
Query 'For coding purposes, for term COVID-19 (LIKE SYMPTOMS), please enter symptoms. One per line' answered with 'SEE DYMPATOM LOG DATA' (Site from System).	System	17 Nov 2020 16:22:53
User entered 'COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 16:22:53
User opened query 'For coding purposes, for term COVID-19 (LIKE SYMPTOMS), please enter symptoms. One per line' (Site from System).	(b) (4)	
Data point term sent to Coder	Melissa Fuson (b) (4)	17 Nov 2020 16:22:21
Coding entries removed.	(b) (4)	
User entered 'COVID-19 (LIKE SYMPTOMS)' reason for change: Data Entry Error	Coder Import (b) (4)	17 Nov 2020 16:19:47
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.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	System	17 Nov 2020 16:10:53
Data point term sent to Coder	Melissa Fuson (b) (4)	17 Nov 2020 16:10:25
User entered 'COVID-19 (LIKE SYMPTOMS)' reason for change: Data Entry Error	(b) (4)	
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.	Melissa Fuson (b) (4)	17 Nov 2020 16:10:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	16 Nov 2020 16:53:46
User entered 'COVID-19'	(b) (4)	
	Coder Import (b) (4)	16 Nov 2020 16:53:46
	(b) (4)	
	System	16 Nov 2020 16:52:57
	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'please indicate yes - all illness visits are medically attended' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:29:32
		18 Nov 2020 18:28:39
User closed query 'Please reconcile as per protocol illness visit is an MAAE' (Site from CRA).		18 Nov 2020 18:28:37
Query 'please indicate yes - all illness visits are medically attended' answered with 'YES' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:40:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:39:20
User opened query 'please indicate yes - all illness visits are medically attended' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:58:48
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:08:57
Query 'Please reconcile as per protocol illness visit is an MAAE' answered with 'UPDATED TO YES. RECONCILE AS PER PROTOCOL ILLNESS VISIT.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 15:45:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 15:44:55
User opened query 'Please reconcile as per protocol illness visit is an MAAE' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:30:25
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

US3412022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:29:36
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

US3412022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:39:21
User closed query 'Please verify response as symptoms of COVID have been captured on the symptom log. Please revise response or clarify discrepancy.' (Site from CRA).		24 Nov 2020 18:39:19
Query 'Please verify response as symptoms of COVID have been captured on the symptom log. Please revise response or clarify discrepancy.' answered with 'UPDATED FROM NO TO YES PER SYMPTON LOG' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 15:25:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 15:24:35
User opened query 'Please verify response as symptoms of COVID have been captured on the symptom log. Please revise response or clarify discrepancy.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 02:10:35
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:53:14
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:53:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:29:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:39:27
User entered '07 Nov 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 19:10:06
User entered '03 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:02
Query 'Per source, symptoms started on 07 Nov 2020 p please confirm and update accordingly' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:38:31
DataPoint Un-verified.		18 Nov 2020 18:31:45
DataPoint Verified.		18 Nov 2020 18:31:36
User opened query 'Per source, symptoms started on 07 Nov 2020 p please confirm and update accordingly' (Site from CRA).		18 Nov 2020 18:31:14
User entered '08 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 21:39:20
User entered '07 Nov 2020'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:17
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

US3412022

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:58:15
DataPoint Un-verified.	Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:39:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 19:10:06
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:51:12
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:12
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:12
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:51:02
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:31:18
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 19:58:13
User closed query 'PV Query: Please confirm the event end date. The query response states event resolved on 20 Oct 2020, however, event onset was reported as 07 Nov 2020.' (Site from Safety). Query 'PV Query: Please confirm the event end date. The query response states event resolved on 20 Oct 2020, however, event onset was reported as 07 Nov 2020.' answered with 'this has been updated to correct end date of 25-Nov-2020' (Site from Safety). User opened query 'PV Query: Please confirm the event end date. The query response states event resolved on 20 Oct 2020, however, event onset was reported as 07 Nov 2020.' (Site from Safety). DataPoint Un-verified.	Steven Anderson (b) (4)	11 Dec 2020 15:36:49
User entered '25 Nov 2020' reason for change: Data Entry Error User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	08 Dec 2020 21:25:40
User entered empty; reason for change Data Entry Error Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with '20 oct 2020 event was resolved confirmed with source ' (Site from Safety). DataPoint Un-verified.	Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
User entered empty; reason for change Data Entry Error Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with '20 oct 2020 event was resolved confirmed with source ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 17:23:34
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Mylene Asmar-Rios (b) (4)	24 Nov 2020 18:39:25
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 19:10:06
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:54:15
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:02
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:02
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:38:13
User entered '20 Oct 2020' reason for change: Data Entry Error User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:31:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:22
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	18 Nov 2020 18:31:36
	(b) (4), (b) (6)	
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 17:23:38
		24 Nov 2020 18:39:31
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'action taken has been updated' (Site from Safety). DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:57:15
	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 18:51:02
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:36:33
		18 Nov 2020 18:31:36
User entered 'None (NONE)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:39:33
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 19:11:56
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	23 Nov 2020 18:57:44
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 18:57:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '1'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:39:35
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 19:11:56
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	23 Nov 2020 18:57:44
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 18:57:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered '0'	Mylene Asmar-Rios	16 Nov 2020 16:52:10
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Jan 2021 03:31:14
DataPoint Un-verified.	Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	08 Dec 2020 17:48:23
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 17:23:42
DataPoint Verified.		
		24 Nov 2020 22:40:28
DataPoint Un-verified.	Steven Anderson (b) (4)	24 Nov 2020 22:36:04
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 22:36:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:39:36
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 19:10:06
	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'event has resolved as of 20 oct 2020' (Site from Safety).	Mylene Asmar-Rios	23 Nov 2020 19:05:54
	(b) (4)	
DataPoint Un-verified.	Mylene Asmar-Rios	23 Nov 2020 18:51:02
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios	23 Nov 2020 18:51:02
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 17:37:53
DataPoint Verified.		
		18 Nov 2020 18:31:36

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'all meds given have been added to con meds' (Site from Safety).	Mylene Asmar-Rios (b) (4)	23 Nov 2020 19:06:25
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 17:37:33
DataPoint Verified.		18 Nov 2020 18:31:36
User entered empty.	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:52:10

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 16:52:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:27:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:39:20
User entered '0'	System	17 Nov 2020 16:08:57
User entered '1'	System	17 Nov 2020 15:44:55
User entered '0'	System	16 Nov 2020 16:52:10

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'please spell out Type 2 Diabetes Mellitus' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:47:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 19:16:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Jan 2021 19:16:57
Data point term sent to Coder	System	21 Jan 2021 18:14:37
Query 'please spell out Type 2 Diabetes Mellitus' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:14:13
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:14:06
User entered 'WORSENING Type II diabetes mellitus' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:14:06
User opened query 'please spell out Type 2 Diabetes Mellitus' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:35:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 05:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 05:34:51
Data point term sent to Coder	System	08 Dec 2020 14:25:21
User entered 'WORSENING T2DM'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'No (N)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'No (N)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '30 Oct 2020'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User entered empty.	System	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	25 Feb 2021 21:12:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	11 Dec 2020 15:37:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Dec 2020 15:37:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Dec 2020 15:37:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 14:24:53
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	25 Feb 2021 21:38:46
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 21:38:46
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 21:12:15
User entered '30 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	25 Feb 2021 21:12:15
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User entered empty.	System	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'None (NONE)'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'I'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[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 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'diverticulitis' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	25 Feb 2021 21:38:46
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	08 Dec 2020 14:24:53
	(b) (4)	

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered 'WORSENING DIABETES (A1C 7.0 5MONTHS AGO AND MOST RECENTLY 13 SAW PCP WHO STARTED INSULIN., ONSET 30-10-2020 WHEN LAST A1C DRAWN BY PCP. MODERATE, NR, IMPROVING FBG. RETURNING TO PCP ON 11-DEC-2020. WILL UPDATE COVID19 AE UPON RECEIPT OF LAB. NO SYMPTOMS.'	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User entered '0'	System	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08
User entered '1'	System	08 Dec 2020 14:24:53

US3412022

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:27:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:44:08

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:08:34
Reviewed for Safety.		23 Feb 2021 13:47:30
User entered 'USA-US061-2021-mRNA-1273-P301000006'	System	03 Feb 2021 17:27:18
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 17:27:18

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:08:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 18:01:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Feb 2021 18:01:30
Data point term sent to Coder	System	02 Feb 2021 17:45:37
User entered 'Diverticulitis'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:08:37
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:08:39
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:08:41
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:08:43
User entered '28 Jan 2021'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:08:50
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Un-verified.	Andrea Newlands (b) (4)	25 Feb 2021 21:11:09
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	25 Feb 2021 21:11:09
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:08:48
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:01:36
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 21:11:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Feb 2021 21:11:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:11:19
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 21:11:09
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:11:09
User entered '02 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:11:09
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:08:52
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).		12 Feb 2021 12:53:17
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:08:54
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Feb 2021 17:44:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:08:55
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:08:59
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:02
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:04
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:08
User entered 'I'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:10
User entered '28 Jan 2021'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 20:47:51
User closed query 'PV Query: Thank you for discharge date confirmation. Please update discharge date in eCRF accordingly (02 Feb 2021).' (Site from Safety).		20 Apr 2021 19:07:19
Query 'PV Query: Thank you for discharge date confirmation. Please update discharge date in eCRF accordingly (02 Feb 2021).' answered with 'this date has been updated per query' (Site from Safety).	Steven Anderson (b) (4)	19 Apr 2021 17:54:13
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	19 Apr 2021 17:53:33
Signature has been broken.	(b) (4)	
	Steven Anderson (b) (4)	19 Apr 2021 17:53:33
User entered '02 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	19 Apr 2021 17:53:33
User opened query 'PV Query: Thank you for discharge date confirmation. Please update discharge date in eCRF accordingly (02 Feb 2021).' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:05:17
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' (Site from Safety).	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 12:32:44
Query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' answered with 'confirmed' (Site from Safety).		17 Mar 2021 15:41:43
User opened query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' (Site from Safety).		11 Mar 2021 16:26:51
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:09:12
User entered '01 Feb 2021'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	03 Mar 2021 12:49:02
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 12:49:02
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	
User entered 'Unknown (UNK)'	System	02 Feb 2021 17:44:37
	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 17:44:37

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:20
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:21
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:23
User entered 'I'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	25 Feb 2021 17:09:51
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:09:45
DataPoint Verified.		25 Feb 2021 17:09:25
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:09:53
DataPoint Un-verified.		25 Feb 2021 17:09:47
DataPoint Verified.		25 Feb 2021 17:09:39
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:10:15
User entered 'None (NONE)'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:10:18
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:29:57
User closed query 'Please add Morphine, Zofran, and Heparin to Con Med CRF as noted in source' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 12:29:55
Query 'Please add Morphine, Zofran, and Heparin to Con Med CRF as noted in source' answered with 'these have been added' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 13:06:55
User opened query 'Please add Morphine, Zofran, and Heparin to Con Med CRF as noted in source' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 13:06:48
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:10:23
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:47:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:58
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 12:54:16
User entered 'I'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:10:26
User entered '0'	Steven Anderson (b) (4)	02 Feb 2021 17:44:37
	(b) (4)	

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Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:51:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
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) (4), (b) (6)	26 Feb 2021 15:01:43
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:11:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 21:11:34
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)	12 Feb 2021 12:53:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	02 Feb 2021 17:44:37

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:52:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
User entered empty.	Steven Anderson (b) (4)	02 Feb 2021 17:44:37

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 20:48:04
DataPoint Un-verified.	Steven Anderson (b) (4)	19 Apr 2021 17:54:49
Signature has been broken.	(b) (4) Steven Anderson (b) (4) (b) (4)	19 Apr 2021 17:54:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'OUR SITE WAS NOTIFIED ON 01-FEB-2021 BY SUBJECT OF HIS ADMISSION INTO HOSPITAL ON 28-JAN-2021 FOR FEVER AND ABDOMINAL PAIN. HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS. HE WAS DISCHARGED ON 02-FEB-2021 AND MEDICAL RECORDS ARE BEING REQUESTED FOR FURTHER FOLLOW UP. SUBJECT PRESENTED TO ED AS A 50Y/O MALE WITH HISTORY OF HTN, T2DM, AND TOBACCO ABUSE WITH ONSET OF LLQ ABDOMINAL PAIN ON 28JAN2021. RECEIVED MRNA-1273 (POST UNBLINDING) ON 06JAN2021 AND 25FEB2021. INITIAL PRESENTATION - FEBRILE 101.4, ELEVATED WBC 13.2, OTHERWISE VITALS STABLE. PHYSICAL EXAM SIGNIFICANT FOR MILD TO MODERATE TENDERNESS LOCALLY TO THE LEFT LOWER QUADRANT. LABS AND STUDIES: 29JAN2021 - WBC 13.2 THOU/MCL WITH REFERENCE RANGE 3.6-10.5 THOU/MCL; 30JAN2021 WBC 11.1; 31JAN2021 WBC 7.8; 01FEB2021 WBC 6.2; IMAGING - CT WITH CONTRAST ABDOMEN PEVIS 29JAN2021 THICKENING/STRANDY SIGMOID COLON WITH SMALL LOCULE IN MISENTERY; BLOOD CULTURE NEGATIVE, UA-WNZ. SUBJECT WAS MANAGED WITH CONSERVATIVE TX WHICH INCLUDED NPA AND THE FOLLOWING MEDS: CIPRO IV, FLAGYL IV, MORPHINE, ZOTRAN, HEPARIN, TYLENOL, MIRALAX, SENOKOT, NOVOLOG. SUBJECT WAS DISCHARGED WITH NEW PRESCRIPTIONS HOWEVER HE NEVER FILLED/TOOK ANY OF THEM. THROUGH OUT HOSPITAL STAY HIS PAIN IMPROVED AND HE WAS DISCHARGED ON 02FEB2021 WITH INSTRUCTIONS TO FOLLOWUP FOR OUTPATIENT COLONOSCOPY IN 6-8 WEEKS. SUBJECT STATES ALL SYMPTOMS HAVE FULLY RESOLVED AND HE IS FEELING WELL.' reason for change: Data Entry Error	Steven Anderson (b) (4)	19 Apr 2021 17:54:49

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:55:27
User closed query 'Per DM CLR: Narrative indicates that subject had "CT WITH CONTRAST ABODMEN PEVIS & BLOOD CULTURE." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		13 Apr 2021 11:01:10
User closed query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' (Site from Safety).		12 Apr 2021 15:06:57
User closed query 'PV Query: Please provide the units of measure and reference range for the WBC.' (Site from Safety).		12 Apr 2021 15:06:48
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:43
Query 'Per DM CLR: Narrative indicates that subject had "CT WITH CONTRAST ABODMEN PEVIS & BLOOD CULTURE." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'this information was uploaded into con procedures' (Site from DM).	(b) (4)	
Query 'PV Query: Please provide the units of measure and reference range for the WBC.' answered with 'this unit of measurement and reference range has been input' (Site from Safety).	Steven Anderson (b) (4)	09 Apr 2021 18:56:25
	(b) (4)	
	Steven Anderson (b) (4)	09 Apr 2021 18:46:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'OUR SITE WAS NOTIFIED ON 01-FEB-2021 BY SUBJECT OF HIS ADMISSION INTO HOSPITAL ON 28-JAN-2021 FOR FEVER AND ABDOMINAL PAIN. HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS. HE WAS DISCHARGED ON 01-FEB-2021 AND MEDICAL RECORDS ARE BEING REQUESTED FOR FURTHER FOLLOW UP. SUBJECT PRESENTED TO ED AS A 50Y/O MALE WITH HISTORY OF HTN, T2DM, AND TOBACCO ABUSE WITH ONSET OF LLQ ABDOMINAL PAIN ON 28JAN2021. RECEIVED MRNA-1273 (POST UNBLINDING) ON 06JAN2021 AND 25FEB2021. INITIAL PRESENTATION - FEBRILE 101.4, ELEVATED WBC 13.2, OTHERWISE VITALS STABLE. PHYSICAL EXAM SIGNIFICANT FOR MILD TO MODERATE TENDERNESS LOCALLY TO THE LEFT LOWER QUADRANT. LABS AND STUDIES: 29JAN2021 - WBC 13.2 THOU/mcL with reference range 3.6-10.5 THOU/mcL; 30JAN2021 WBC 11.1; 31JAN2021 WBC 7.8; 01FEB2021 WBC 6.2; IMAGING - CT WITH CONTRAST ABDOMEN PEVIS 29JAN2021 THICKENING/STRANDY SIGMOID COLON WITH SMALL LOCULE IN MISENTERY; BLOOD CULTURE NEGATIVE, UA-WNZ. SUBJECT WAS MANAGED WITH CONSERVATIVE TX WHICH INCLUDED NPA AND THE FOLLOWING MEDS: CIPRO IV, FLAGYL IV, MORPHINE, ZOTRAN, HEPARIN, TYLENOL, MIRALAX, SENOKOT, NOVOLOG. SUBJECT WAS DISCHARGED WITH NEW PRESCRIPTIONS HOWEVER HE NEVER FILLED/TOOK ANY OF THEM. THROUGH OUT HOSPITAL STAY HIS PAIN IMPROVED AND HE WAS DISCHARGED ON 02FEB2021 WITH INSTRUCTIONS TO FOLLOWUP FOR OUTPATIENT COLONOSCOPY IN 6-8 WEEKS. SUBJECT STATES ALL SYMPTOMS HAVE FULLY RESOLVED AND HE IS FEELING WELL.' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 18:45:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' answered with 'subject discharged 02FEB2021' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:16:20
User opened query 'Per DM CLR: Narrative indicates that subject had "CT WITH CONTRAST ABODMEN PEVIS & BLOOD CULTURE." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		24 Mar 2021 11:39:28
User opened query 'PV Query: Please confirm the discharge date. It was reported as 01 Feb 2021 however, it was also noted in the narrative the subject was discharged on 02 Feb 2021.' (Site from Safety).		18 Mar 2021 18:01:36
User opened query 'PV Query: Please provide the units of measure and reference range for the WBC.' (Site from Safety).		18 Mar 2021 18:01:30
User closed query 'PV Query: Please provide the units of measure and reference range for the WBC.' (Site from Safety).		18 Mar 2021 12:32:49
User closed query 'Per DM CLR: Per SAE Narrative "HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS". However, there is no IV antibiotic noted in the CM eCRF. Update as appropriate.' (Site from DM).		18 Mar 2021 05:11:04
Query 'Per DM CLR: Per SAE Narrative "HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS". However, there is no IV antibiotic noted in the CM eCRF. Update as appropriate.' answered with 'updated' (Site from DM).		17 Mar 2021 16:51:52
Query 'PV Query: Please provide the units of measure and reference range for the WBC.' answered with 'updated' (Site from Safety).		17 Mar 2021 16:51:44
User opened query 'Per DM CLR: Per SAE Narrative "HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS". However, there is no IV antibiotic noted in the CM eCRF. Update as appropriate.' (Site from DM).		14 Mar 2021 17:48:17

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the units of measure and reference range for the WBC.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:23:55
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		04 Mar 2021 15:55:51
User closed query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		04 Mar 2021 15:55:45

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'OUR SITE WAS NOTIFIED ON 01-FEB-2021 BY SUBJECT OF HIS ADMISSION INTO HOSPITAL ON 28-JAN-2021 FOR FEVER AND ABDOMINAL PAIN. HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS. HE WAS DISCHARGED ON 01-FEB-2021 AND MEDICAL RECORDS ARE BEING REQUESTED FOR FURTHER FOLLOW UP. SUBJECT PRESENTED TO ED AS A 50Y/O MALE WITH HISTORY OF HTN, T2DM, AND TOBACCO ABUSE WITH ONSET OF LLQ ABDOMINAL PAIN ON 28JAN2021. RECEIVED MRNA-1273 (POST UNBLINDING) ON 06JAN2021 AND 25FEB2021. INITIAL PRESENTATION - FEBRILE 101.4, ELEVATED WBC 13.2, OTHERWISE VITALS STABLE. PHYSICAL EXAM SIGNIFICANT FOR MILD TO MODERATE TENDERNESS LOCALLY TO THE LEFT LOWER QUADRANT. LABS AND STUDIES: 29JAN2021 - WBC 13.2; 30JAN2021 WBC 11.1; 31JAN2021 WBC 7.8; 01FEB2021 WBC 6.2; IMAGING - CT WITH CONTRAST ABODMEN PEVIS 29JAN2021 THICKENING/STRANDY SIGMOID COLON WITH SMALL LOCULE IN MISENTERY; BLOOD CULTURE NEGATIVE, UA-WNZ. SUBJECT WAS MANAGED WITH CONSERVATIVE Tx WHICH INCLUDED NPA AND THE FOLLOWING MEDS: CIPRO IV, FLAGYL IV, MORPHINE, ZOTRAN, HEPARIN, TYLENOL, MIRALAX, SENOKOT, NOVOLOG. SUBJECT WAS DISCHARGED WITH NEW PRESCRIPTIONS HOWEVER HE NEVER FILLED/TOOK ANY OF THEM. THROUGH OUT HOSPITAL STAY HIS PAIN IMPROVED AND HE WAS DISCHARGED ON 02FEB2021 WITH INSTRUCTIONS TO FOLLOWUP FOR OUTPATIENT COLONOSCOPY IN 6-8 WEEKS. SUBJECT STATES ALL SYMPTOMS HAVE FULLY RESOLVED AND HE IS FEELING WELL.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 03 Mar 2021 13:21:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Andrea Newlands (b) (4)	(b) (4) 03 Mar 2021 13:19:56
	Andrea Newlands (b) (4)	(b) (4) 03 Mar 2021 13:19:49
User entered 'OUR SITE WAS NOTIFIED ON 01-FEB-2021 BY SUBJECT OF HIS ADMISSION INTO HOSPITAL ON 28-JAN-2021 FOR FEVER AND ABDOMINAL PAIN. HE WAS DIAGNOSED WITH DIVERTICULITIS AND TREATED WITH IV ANTIBIOTICS. HE WAS DISCHARGED ON 01-FEB-2021 AND MEDICAL RECORDS ARE BEING REQUESTED FOR FURTHER FOLLOW UP. subject presented to ED as a 50y/o male with history of htn, t2dm, and tobacco abuse with onset of LLQ abdominal pain on 28jan2021. received mRNA-1273 (post unblinding) on 06jan2021 and 25feb2021. initial presentation - febrile 101.4, elevated wbc 13.2, otherwise vitals stable. physical exam significant for mild to moderate tenderness locally to the left lower quadrant. labs and studies: 29jan2021 - wbc 13.2; 30jan2021 wbc 11.1; 31jan2021 wbc 7.8; 01feb2021 wbc 6.2; imsging - ct with out contrast abodmen pevis 29jan2021 thickening/strandy sigmoid colon with small locule in misentery; blood culture negative, ua-wnz. subject was managed without conservative tc which included NPA and the following meds: cipro iv, flagyl iv, morphine, zotran, heparin, tylenol, miralax, senokot, novolog. subject was discharged with new prescriptions however he never filled/took any of them. through out hospital stay his pain improved and he was discharged on 02feb2021 with instructions to followup for outpatient colonoscopy in 6-8 weeks. subject states all symptoms have fully resolved and he is feeling well.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 03 Mar 2021 13:19:49

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'not done' (Site from Safety). DataPoint Verified.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:49:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 17:10:44
User opened query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		12 Feb 2021 12:53:47
User entered 'OUr site was notified on 01-feb-2021 by subject of his admission into hospital on 28-Jan-2021 for fever and abdominal pain. he was diagnosed with diverticulitis and treated with IV antibiotics. he was discharged on 01-feb-2021 and medical records are being requested for further follow up.'	Steven Anderson (b) (4) (b) (4)	12 Feb 2021 12:52:54 02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 17:44:37

US3412022

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:27:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Feb 2021 17:44:37

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:27:21

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User closed query 'please add glipizide started 04 Nov 202 for worsening diabetes mellitus type 2' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 23:49:50
Query 'please add glipizide started 04 Nov 202 for worsening diabetes mellitus type 2' answered with 'this has been added. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:53
User opened query 'please add glipizide started 04 Nov 202 for worsening diabetes mellitus type 2' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:42:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:02:35
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 14:34:53

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:23:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:23:18
Data point term sent to Coder	System	13 Aug 2020 19:04:59
User entered 'METFORMIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'DM2'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '1000'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:47:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:04:58
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Sep 2020 19:55:15
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '2 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Sep 2020 19:55:15
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User entered '2'	System	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User entered '1'	System	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:36
User entered '804 (804)'	System	13 Aug 2020 19:04:58

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:36:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:36:17
Data point term sent to Coder	System	13 Aug 2020 19:07:01
User entered 'FUROSEMIDE'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'PERIPHERAL EDEMA SWELLING'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '20'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:47:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:06:09
User entered 'UN Mar 2020'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:06:09

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:09:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:09:23
Data point term sent to Coder	System	13 Aug 2020 19:08:05
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'HYPERTENSION'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '40'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:47:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:07:17
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:07:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 07:07:34
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 Oct 2020 07:07:34
Data point term sent to Coder	System	30 Sep 2020 19:57:56
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	30 Sep 2020 19:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:30:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:30:39
Data point term sent to Coder	System	30 Sep 2020 19:29:52
Coding entries removed.	Mylene Asmar-Rios (b) (4)	30 Sep 2020 19:28:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:09:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 19:09:24
Data point term sent to Coder	System	13 Aug 2020 19:09:10
User entered 'SIMVASTATIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User closed query 'Per DM CLR: Please update the indication to reflect the abnormality/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).		12 Oct 2020 17:50:22
User entered 'HYPERLIPIDEMIA - CHOLESTEROL' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Sep 2020 19:57:34
Query 'Per DM CLR: Please update the indication to reflect the abnormality/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' answered with 'OK' (Site from DM).	Mylene Asmar-Rios (b) (4)	30 Sep 2020 19:29:19
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	30 Sep 2020 19:28:54
User opened query 'Per DM CLR: Please update the indication to reflect the abnormality/diagnosis related to CHOLESTEROL. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:31:48
User entered 'CHOLESTEROL'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '10'	Mylene Asmar-Rios	13 Aug 2020 19:08:13
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:47:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:08:13
User entered 'UN Dec 2019'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:08:13

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: ESCITALOPRAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:19:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:19:16
Data point term sent to Coder	System	17 Nov 2020 13:40:47
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 13:40:03
User entered 'ESCITALOPRAN' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 13:40:03
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)	14 Aug 2020 00:14:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:14:11
Data point term sent to Coder	System	13 Aug 2020 19:10:13
User entered 'ESCITALOPRAM'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'ANXIETY, DEPRESSION'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '20'	Mylene Asmar-Rios	13 Aug 2020 19:09:28
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:47:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 19:09:28
User entered 'UN UNK 2014'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 19:09:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:19:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' (Site from DM).		22 Jan 2021 11:25:57
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' answered with 'this is not due to worsening Diabetes type II' (Site from DM).	Jacob sekinger (b) (4)	21 Jan 2021 18:12:37
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:28:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE, PRODUCTSYNONYM: JANUMET XR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 20:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Sep 2020 20:00:42
Data point term sent to Coder	System	30 Sep 2020 20:00:00
User entered 'JANUMET XR'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:41
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:19:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' canceled (Site from DM).		07 Jan 2021 16:28:18
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES TYPE II should be recorded, and update con med indication or provide clarification. ' (Site from DM).		07 Jan 2021 16:28:16
User entered 'DIABETES TYPE II'	Melissa Fuson (b) (4) (b) (4)	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:19:49
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User closed query 'Per CDM RQ: Response noted. However, please confirm that dose per administration is correct as it not the same as the query response. Thank you.' (Site from DM).		24 Nov 2020 13:19:23
Query 'Per CDM RQ: Response noted. However, please confirm that dose per administration is correct as it not the same as the query response. Thank you.' answered with 'confirmed with source and updated info' (Site from DM).	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:16:49
User entered '100/1000' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	23 Nov 2020 16:16:31
User opened query 'Per CDM RQ: Response noted. However, please confirm that dose per administration is correct as it not the same as the query response. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:28:09
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/1000).		23 Nov 2020 15:28:09
' (Site from DM).		
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/1000).	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:40:28
' answered with 'updated dose 100/1000' (Site from DM).		
User entered '100/100' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Nov 2020 16:40:18
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 100/1000).	(b) (4), (b) (6)	16 Nov 2020 12:10:15
' (Site from DM).		

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Melissa Fuson (b) (4) (b) (4)	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:52
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:54
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:19:56
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:57
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:20:01
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:20:03
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:20:09
DataPoint Verified.		25 Feb 2021 17:14:38
User entered '2 Sep 2020'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:20:11
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:20:13
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:20:17
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:20:19
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	30 Sep 2020 19:59:15
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 19:59:15

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:19:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 13:37:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 13:37:46
Data point term sent to Coder	System	17 Nov 2020 13:36:44
User entered 'FLONASE'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:03
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:05
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'SEASONAL ALLERGIES'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:07
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '2'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:12
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'puff (PUFF)'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:14
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:16
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:18
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:19:23
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Nasal (NASAL)'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:25
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:26
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'UN UNK 1990'	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:19:28
DataPoint Verified.		25 Feb 2021 17:14:38
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:19:30
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:19:32
DataPoint Verified.		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:36:21
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:19:35
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 13:36:21

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:18:18
DataPoint Verified.		25 Feb 2021 17:14:38
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: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 02:09:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Nov 2020 02:09:05
Data point term sent to Coder	System	24 Nov 2020 15:23:41
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 15:23:19
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'active ingredient loratadine' (Site from System).	Melissa Fuson (b) (4)	24 Nov 2020 15:23:19
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	24 Nov 2020 14:52:09
Data point term sent to Coder	System	17 Nov 2020 13:39:47
User entered 'CLARITAN (OTC)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:23
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:25
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'SEASONAL ALLERGIES'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:18:27
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '10'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:18:35
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:36
DataPoint Verified.		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:38
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:39
DataPoint Verified.		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	25 Feb 2021 17:18:41
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:44
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:46
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'UN UNK 1990'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:48
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:52
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:54
DataPoint Verified.	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:55
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Nov 2020 13:39:01
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:39:01

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 13:39:01

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 13:39:01

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:29:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:29:42
Data point term sent to Coder Coding entries removed.	System	03 Mar 2021 12:53:41
	Andrea Newlands (b) (4)	03 Mar 2021 12:52:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 12:51:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 12:51:57
Data point term sent to Coder Coding entries removed.	System	03 Mar 2021 12:51:40
	Andrea Newlands (b) (4)	03 Mar 2021 12:51:21
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:37
DataPoint Verified.		25 Feb 2021 17:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:46:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 22:46:50
Data point term sent to Coder	System	08 Dec 2020 14:18:16
User entered 'NOVOLOG'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:39
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'worsening TYPE 2 DIABETES' reason for change: Data Entry Error	(b) (4)	
User entered 'type 2 DIABETES' reason for change: Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 12:52:53
DataPoint Un-verified.	(b) (4)	03 Mar 2021 12:51:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:42
User entered 'WORSENING DIABETES'	Melissa Fuson (b) (4)	25 Feb 2021 17:14:38
	(b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:44
DataPoint Verified.		25 Feb 2021 17:14:38
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).		19 Feb 2021 04:57:01
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'entry error, updated' (Site from DM).	Andrea Newlands (b) (4)	18 Feb 2021 17:26:25
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:22:18
User entered '15'	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User closed query 'Per CDM re-query: Dose unit is Other - Unit. Please review if the pre defined option 'IU' is more appropriate to choose for dose unit. If yes, update as appropriate else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 05:04:09
Query 'Per CDM re-query: Dose unit is Other - Unit. Please review if the pre defined option 'IU' is more appropriate to choose for dose unit. If yes, update as appropriate else clarify. Thank you.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:51:47
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 Mar 2021 12:51:42
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	03 Mar 2021 12:51:32
User entered 'IU (IU)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:51:32
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:50
DataPoint Verified.		25 Feb 2021 17:14:38
User opened query 'Per CDM re-query: Dose unit is Other - Unit. Please review if the pre defined option 'IU' is more appropriate to choose for dose unit. If yes, update as appropriate else clarify. Thank you.' (Site from DM).		19 Feb 2021 04:56:58
User entered 'Other (OTHER)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 17:26:14
User entered 'ug (ug)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	03 Mar 2021 12:51:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:51
User entered 'units' reason for change: Data Entry Error	(b) (4)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4)	18 Feb 2021 17:26:14
	(b) (4)	
	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:53
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:55
DataPoint Verified.		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:17:57
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Subcutaneous (SUBCUTANEOUS)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:17:58
DataPoint Verified.		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:18:08
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '04 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:06
DataPoint Verified.		25 Feb 2021 17:14:38
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	25 Feb 2021 21:39:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:18:05
		25 Feb 2021 17:14:38
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 14:17:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 14:17:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	08 Dec 2020 14:17:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Dec 2020 14:17:26
	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '30 Jan 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	25 Feb 2021 21:39:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:18:03
		25 Feb 2021 17:14:38
User entered empty.	Melissa Fuson (b) (4)	08 Dec 2020 14:17:26
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:18:02
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User entered '3'	System	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User entered '1'	System	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:22
User entered '804 (804)'	System	08 Dec 2020 14:17:26

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 08:42:02
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 Mar 2021 08:42:02
Data point term sent to Coder	System	03 Mar 2021 12:53:41
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:53:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:29:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 00:29:18
Data point term sent to Coder	System	21 Jan 2021 18:12:30
User entered 'glipizide'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:34:38
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'this has been updated ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 19:00:37
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 18:58:05
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 18:58:05
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:49:23
DataPoint Verified.		25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	03 Mar 2021 12:53:01
	(b) (4)	
User entered 'worsening TYPE 2 DIABETES'	Andrea Newlands (b) (4)	03 Mar 2021 12:53:01
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'worsening Diabetes Mellitus II'	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '5'	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'once daily (QD)'	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '04 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Jacob sekinger (b) (4)	21 Jan 2021 18:11:39
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Jan 2021 18:11:39

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 13:57:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 13:57:58
Data point term sent to Coder	System	22 Feb 2021 13:57:11
User entered 'amoxicillin'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'diverticulitis'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered '500'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'twice daily (BID)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered '01 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered '0'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:41:59
User closed query 'per source stop date = 05 Feb 2021? Please confirm and update accordingly' (Site from CRA).		11 Mar 2021 00:41:55
Query 'per source stop date = 05 Feb 2021? Please confirm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	26 Feb 2021 13:21:42
DataPoint Un-verified.	Andrea Newlands (b) (4)	26 Feb 2021 13:21:38
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	26 Feb 2021 13:21:38
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:16:52
User opened query 'per source stop date = 05 Feb 2021? Please confirm and update accordingly' (Site from CRA).		25 Feb 2021 17:15:46
DataPoint Un-verified.		25 Feb 2021 17:15:12
Query 'please confirm - per source for 5 days?' canceled (Site from CRA).		25 Feb 2021 17:15:08
DataPoint Verified.		25 Feb 2021 17:14:38
DataPoint Un-verified.		25 Feb 2021 17:12:03
DataPoint Verified.		25 Feb 2021 17:11:55
User opened query 'please confirm - per source for 5 days?' (Site from CRA).		25 Feb 2021 17:11:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:42:04
DataPoint Un-verified.	Andrea Newlands (b) (4)	26 Feb 2021 13:21:38
User entered '05 Feb 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Andrea Newlands (b) (4)	26 Feb 2021 13:21:38
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 17:16:52
DataPoint Verified.		25 Feb 2021 17:15:18
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 13:56:59
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:11:55
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User entered '2'	System	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User entered '1'	System	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:31:56
User entered '804 (804)'	System	22 Feb 2021 13:56:59

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Mar 2021 12:06:37
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 Mar 2021 12:06:37
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Data point term sent to Coder	System	22 Feb 2021 14:00:18
User entered 'oxycodone'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'diverticulitis'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '5'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '01 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:59:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:19:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 13:19:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 13:59:19
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
DataPoint Verified.	(b) (4)	15 Apr 2021 12:59:55
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:19:30
	(b) (4)	
User entered '05 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	26 Feb 2021 13:19:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 13:59:19
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User entered empty.	System	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User entered empty.	System	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:05
User entered empty.	System	22 Feb 2021 13:59:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:31:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:31:32
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
Data point term sent to Coder	System	22 Feb 2021 14:02:19
User entered 'senekot'	Andrea Newlands (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'diverticulitis'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:42:25
User closed query 'per source this is 2 8.6 mg tablets so should be 17.2 mg? Please ocnifrm and update accordingly' (Site from CRA).		11 Mar 2021 00:42:22
Query 'per source this is 2 8.6 mg tablets so should be 17.2 mg? Please ocnifrm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	26 Feb 2021 13:20:10
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:20:05
User entered '17.2' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:20:05
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:16:52
DataPoint Un-verified.		25 Feb 2021 17:16:01
DataPoint Verified.		25 Feb 2021 17:14:38
User opened query 'per source this is 2 8.6 mg tablets so should be 17.2 mg? Please ocnifrm and update accordingly' (Site from CRA).		25 Feb 2021 17:14:06
User entered '8.6'	Andrea Newlands (b) (4)	22 Feb 2021 14:01:19
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'twice daily (BID)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '01 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:00:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:21:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 13:21:55
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 14:01:19
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:00:14
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	26 Feb 2021 13:21:55
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	26 Feb 2021 13:20:27
DataPoint Un-verified.	Andrea Newlands (b) (4)	26 Feb 2021 13:20:27
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 13:20:27
DataPoint Verified.	Andrea Newlands (b) (4)	26 Feb 2021 13:20:27
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
	Andrea Newlands (b) (4)	22 Feb 2021 14:01:19
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User entered '2'	System	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User entered '1'	System	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:37
User entered '804 (804)'	System	22 Feb 2021 14:01:19

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 14:04:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 14:04:58
Data point term sent to Coder	System	22 Feb 2021 14:04:20
User entered 'miralax'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'diverticulitis'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '17'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'g (g)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '01 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:00:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:20:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 13:20:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 14:03:40
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:00:27
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) Andrea Newlands (b) (4)	26 Feb 2021 13:20:47
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	26 Feb 2021 13:20:47
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User entered empty.	System	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User entered empty.	System	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:32:20
User entered empty.	System	22 Feb 2021 14:03:40

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 14:07:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 14:07:19
Data point term sent to Coder	System	22 Feb 2021 14:06:26
User entered 'tylenol'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'diverticulitis'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '325'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:26:12
User closed query '29 Jan 2021 per source? Please confirm and update accordingly' (Site from CRA).		16 Apr 2021 12:26:11
Query '29 Jan 2021 per source? Please confirm and update accordingly' answered with 'this has been updated per query' (Site from CRA).	Steven Anderson (b) (4)	15 Apr 2021 14:13:25
Signature has been broken.	(b) (4)	
	Steven Anderson (b) (4)	15 Apr 2021 14:13:16
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	15 Apr 2021 14:13:16
User opened query '29 Jan 2021 per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 13:01:19
DataPoint Un-verified.		15 Apr 2021 13:00:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '01 Feb 2021'		
	Andrea Newlands (b) (4)	22 Feb 2021 14:06:17
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
DataPoint Verified.	(b) (4)	15 Apr 2021 13:02:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:20:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	26 Feb 2021 13:20:57
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 14:06:17
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:02:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Un-verified.	(b) (4) Andrea Newlands (b) (4)	26 Feb 2021 13:20:57
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	26 Feb 2021 13:20:57
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:14:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User entered empty.	System	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User entered empty.	System	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:33:07
User entered empty.	System	22 Feb 2021 14:06:17

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:02:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN, PRODUCTSYNONYM: CIPRO [CIPROFLOXACIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:58:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Mar 2021 11:58:49
Data point term sent to Coder	System	03 Mar 2021 12:55:41
User entered 'cipro'	Andrea Newlands (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:02:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:02:53
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'diverticulitis'	Andrea Newlands (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:02:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '400'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'mg (mg)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 12:55:28
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:07
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'twice daily (BID)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:11
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:19
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:03:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 12:55:28
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4)	15 Apr 2021 13:03:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '29 Jan 2021'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:03:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '01 Feb 2021'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
DataPoint Verified.		15 Apr 2021 13:03:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
User entered '2'	System	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
User entered '1'	System	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:35:05
User entered '804 (804)'	System	03 Mar 2021 12:55:28

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:03:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 08:38:56
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 Mar 2021 08:38:56
Data point term sent to Coder	System	03 Mar 2021 13:04:53
User entered 'flagyl'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.	(b) (4)	15 Apr 2021 13:03:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:03:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'diverticulitis'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:03:54
User signature succeeded.	Richard Powell (b) (4)	2 Apr 2021 14:12:28
User entered '500'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:03:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'mg (mg)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:03:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 13:04:45
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:04:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'three times daily (TID)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:04:06
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 13:04:45
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:04:10
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:04:12
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 13:04:45
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:04:14
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '29 Jan 2021'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.		15 Apr 2021 13:04:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:04:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:04:23
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '01 Feb 2021'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 13:04:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 13:04:45
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
User entered '3'	System	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
User entered '1'	System	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:30
User entered '804 (804)'	System	03 Mar 2021 13:04:45

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 13:06:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:06:57
Data point term sent to Coder	System	03 Mar 2021 13:05:54
User entered 'novolog'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'type 2 diabetes'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '4'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'IU (IU)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'once (ONCE)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	03 Mar 2021 13:05:33
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered empty.	(b) (4)	03 Mar 2021 13:05:33
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '01 Feb 2021'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '0'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered '01 Feb 2021'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:28
User entered 'No (N)'	Andrea Newlands (b) (4)	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User entered empty.	System	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User entered empty.	System	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:34:20
User entered empty.	System	03 Mar 2021 13:05:33

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:26:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:20:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:20:06
Data point term sent to Coder	System	15 Apr 2021 14:19:08
Data point term sent to Coder	System	15 Apr 2021 14:15:02
User entered 'morphine'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:26:54
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4)	16 Apr 2021 12:27:17
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 12:27:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:26:59
User entered 'Diverticulitis'	Steven Anderson (b) (4)	5 Apr 2021 14:14:38
	(b) (4)	

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:19
User entered '4'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:21
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:26
User entered 'as needed (PRN)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:29
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:31
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:19:00
User entered 'Oral (ORAL)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:37
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:39
User entered '29 Jan 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:41
User entered '0'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:43
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:45
User entered '29 Jan 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:27:49
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User entered empty.	System	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User entered empty.	System	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:55
User entered empty.	System	15 Apr 2021 14:14:38

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 15:19:47
Data point term sent to Coder	System	15 Apr 2021 14:16:04
User entered 'Zofran'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:02
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:04
User entered 'Diverticulitis'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:09
User entered '4'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:11
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:13
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:14
User entered 'as needed (PRN)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:18
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:27
User entered '29 Jan 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:29
User entered '0'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:31
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:35
User entered '29 Jan 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:37
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User entered empty.	System	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User entered empty.	System	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:44
User entered empty.	System	15 Apr 2021 14:15:50

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:29:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:29:43
Data point term sent to Coder	System	15 Apr 2021 14:18:07
User entered 'Heparin'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:46
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:48
User entered 'Diverticulitis'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:51
User entered '5000'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:53
User entered 'IU (IU)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:56
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:28:59
User entered 'as needed (PRN)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:06
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:08
User entered 'Subcutaneous (SUBCUTANEOUS)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:11
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:16
User entered '29 Jan 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:17
User entered '0'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:22
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:24
User entered '1 Feb 2021'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:29:26
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User entered empty.	System	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User entered empty.	System	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:27:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:30:24
User entered empty.	System	15 Apr 2021 14:17:54

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:27:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
Signature has been broken.	Steven Anderson (b) (4)	09 Apr 2021 18:50:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 18:50:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:06:58
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 14:34:35

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
	(b) (4)	
User entered '29 Jan 2021'	Steven Anderson (b) (4)	09 Apr 2021 18:50:47
	(b) (4)	

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
	(b) (4)	
User entered 'CT WITH CONTRAST ABODMEN PEVIS'	Steven Anderson (b) (4)	09 Apr 2021 18:50:47
	(b) (4)	

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
	(b) (4)	
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	09 Apr 2021 18:50:47
	(b) (4)	

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:27:21

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	09 Apr 2021 18:50:47
	(b) (4)	

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
User entered '29 Jan 2021'	Steven Anderson (b) (4)	09 Apr 2021 18:52:05

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
User entered 'BLOOD CULTURE.'	Steven Anderson (b) (4)	09 Apr 2021 18:52:05

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	09 Apr 2021 18:52:05

US3412022

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:27:21

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:34
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:30
User entered empty.	Steven Anderson (b) (4)	09 Apr 2021 18:52:05

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'USA-US061-2020-MRNA-1273-P301000011'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4)	18 Nov 2020 18:32:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gregory'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gottschlich'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '4260 Glendale Milford Road'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Cincinnati'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '45242'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:06
DataPoint Verified.		18 Nov 2020 18:32:35
User entered 'US'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Dec 2020 18:06:17
User entered '2'	System	01 Dec 2020 17:23:17
User entered '1'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'USA-US061-2020-MRNA-1273-P301000011'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gregory'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gottschlich'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '4260 Glendale Milford Road'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Cincinnati'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:50
User entered '45242'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:06
DataPoint Verified.		18 Nov 2020 18:32:35
User entered 'US'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Dec 2020 18:06:17
User entered '2'	System	01 Dec 2020 17:23:17
User entered '1'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
User entered '17/Nov/2020 16:48'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 17:23:06
DataPoint Verified.		18 Nov 2020 18:32:35
User entered '1'		17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'USA-US061-2020-MRNA-1273-P301000011'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4)	18 Nov 2020 18:32:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gregory'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gottschlich'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '4260 Glendale Milford Road'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Cincinnati'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 16:47:50
User entered '45242'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:06
DataPoint Verified.		18 Nov 2020 18:32:35
User entered 'US'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Dec 2020 18:06:17
User entered '2'	System	01 Dec 2020 17:23:17
User entered '1'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:25:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '01/Dec/2020 17:23'	(b) (4) System	01 Dec 2020 17:23:17

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:25:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:17

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'USA-US061-2020-MRNA-1273-P301000011'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'No (N)'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gregory'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Gottschlich'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '4260 Glendale Milford Road'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered 'Cincinnati'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:13
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:32:35
Reviewed for Safety.		17 Nov 2020 16:47:50
User entered '45242'	System	17 Nov 2020 16:47:23

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 17:23:06
DataPoint Verified.		18 Nov 2020 18:32:35
User entered 'US'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	14 Dec 2020 18:06:17
User entered '2'	System	01 Dec 2020 17:23:17
User entered '1'	System	17 Nov 2020 16:48:03

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:25:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '14/Dec/2020 12:06'	(b) (4) System	14 Dec 2020 18:06:17

US3412022

Folder: SAE USA-US061-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:25:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 18:06:17

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '03/Feb/2021 12:28'	(b) (4) System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'I'		03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '23/Feb/2021 08:47'	(b) (4) System	23 Feb 2021 13:47:59

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 13:48:06
User entered 'I'		23 Feb 2021 13:47:59

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '26/Feb/2021 09:02'	(b) (4) System	26 Feb 2021 15:02:26

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:41:01
User entered 'I'		26 Feb 2021 15:02:26

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
User entered '04/Mar/2021 10:40'	(b) (4) System	04 Mar 2021 15:40:38

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:41:01
User entered 'I'		04 Mar 2021 15:40:38

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered '12/Apr/2021 06:15'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'USA-US061-2021-MRNA-1273-P301000006'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'No (N)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Yes (Y)'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Richard'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gregory'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered 'Powell'	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Gottschlich'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '4260 Glendale Milford Road'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'Cincinnati'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:07:23
User entered 'OH'	System	12 Apr 2021 13:15:08

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:07:23
Un-reviewed for Safety.	System	12 Apr 2021 13:15:08
DataPoint Un-verified.	System	12 Apr 2021 13:15:08
Signature has been broken.	System	12 Apr 2021 13:15:08
User entered empty.	System	12 Apr 2021 13:15:08
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered '45242'	System	03 Feb 2021 17:27:18

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 15:07:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 17:29:25
User entered 'US'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:27:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	20 Apr 2021 13:22:15
User entered '5'	System	12 Apr 2021 13:15:08
User entered '4'	System	04 Mar 2021 15:40:38
User entered '3'	System	26 Feb 2021 15:02:26
User entered '2'	System	23 Feb 2021 13:47:59
User entered '1'	System	03 Feb 2021 17:28:41

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:27:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:24
User entered '20/Apr/2021 06:22'	(b) (4) System	20 Apr 2021 13:22:15

US3412022

Folder: SAE USA-US061-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:27:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:22:15