

US3412012 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:39:31

All time stamps listed in this document are displayed in GMT

US3412012

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

[Participant ID](#)

US3412012

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

US3412012

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

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 04:21:09

Generated On: 11 Aug 2021 22:39:31

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

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 04:21:09

Generated On: 11 Aug 2021 22:39:31

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 04:21:09

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	CHRONIC SWELLING LOWER EXTREMITIES NON PITTING EDEMA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	NAUSEA ASSOCIATED WITH MEDS
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
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 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	OPIOD USE DISORDER REMISSION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
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 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	HEPATITIS A
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	ENDOMETRIOSIS
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Condition	OBESITY
Start date (dd MMM yyyy)	29 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412012

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

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>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Height (<i>xxx.x</i>)	168.1 cm
Weight (<i>xxx.x</i>)	117.7 kg
BMI (<i>xxx.x</i>)	41.65250 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 04:21:09

Generated On: 11 Aug 2021 22:39:31

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: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Date of assessment (dd MMM yyyy) 29 JUL 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	29 JUL 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

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

LIVES WITH CONSTRUCTION
WORKER AND RESTURANT
EMPLOYEE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:09

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

Visit date (dd MMM yyyy)	29 JUL 2020
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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	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

What was the participant's randomization number? 142256

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 00:40:40

Generated On: 11 Aug 2021 22:39:31

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 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Temperature (xxx.x)	36.7 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	13:41 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:41
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 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 00:40:40

Generated On: 11 Aug 2021 22:39:31

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: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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) 13:10 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 13:10

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	12:40 (24 HR)
Collection date and time (derived)	29 JUL 2020 12:40

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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	12:35	29 JUL 2020 12:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 13:50

PC Open Date & Time

29 JUL 2020 13:30

PC Close Date & Time

29 JUL 2020 16:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °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	29 JUL 2020 21:07
PC Open Date & Time	29 JUL 2020 16:55
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

30 JUL 2020 21:28

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: 11 Aug 2021 22:39:31

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

98.0 °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 JUL 2020 20:51

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 AUG 2020 21:17

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 06:16

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 21:20

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 21:00

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

29 JUL 2020 13:50

PC Open Date & Time

29 JUL 2020 13:30

PC Close Date & Time

29 JUL 2020 16:00

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

29 JUL 2020 21:08

PC Open Date & Time

29 JUL 2020 16:55

PC Close Date & Time

30 JUL 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 21:29

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 20:52

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

01 AUG 2020 21:18

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 06:17

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 21:20

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 21:00

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 13:51
PC Open Date & Time	29 JUL 2020 13:30
PC Close Date & Time	29 JUL 2020 16:00

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 21:09
PC Open Date & Time	29 JUL 2020 16:55
PC Close Date & Time	30 JUL 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 ☒

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 20:53
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 ☒

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:18
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 06:17
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

61 of 3096

EAB) (1725)

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:20
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 ☒

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 8

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

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 AUG 2020 21:01

PC Open Date & Time 05 AUG 2020 12:00

PC Close Date & Time 06 AUG 2020 11:59

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 AUG 2020 21:01
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:09

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 15 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 15 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 22 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 22 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

Visit date (dd MMM yyyy)	26 AUG 2020
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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	VISIT2
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US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	10:26 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:26
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	11:56 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:56
Temperature (xxx.x)	97.6 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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) 11:20 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 11:20

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

US3412012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

10:55 (24 HR)

Collection date and time (derived)

26 AUG 2020 10:55

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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	10:50	26 AUG 2020 10:50
Nasopharyngeal Swab 2	No		

US3412012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 26 AUG 2020 12:01

PC Open Date & Time 26 AUG 2020 11:40

PC Close Date & Time 26 AUG 2020 14:10

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 96.5 °F

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

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

PC Time Stamp	26 AUG 2020 21:33
PC Open Date & Time	26 AUG 2020 15:05
PC Close Date & Time	27 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 22:57

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 21:28

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 AUG 2020 21:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

30 AUG 2020 22:24

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

31 AUG 2020 21:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

97.4 °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

01 SEP 2020 21:04

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 12:01

PC Open Date & Time

26 AUG 2020 11:40

PC Close Date & Time

26 AUG 2020 14:10

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 21:34

PC Open Date & Time

26 AUG 2020 15:05

PC Close Date & Time

27 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 22:56

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 21:27

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 21:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 22:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 21:02

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

01 SEP 2020 21:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 11:40
PC Close Date & Time	26 AUG 2020 14:10

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 21:35
PC Open Date & Time	26 AUG 2020 15:05
PC Close Date & Time	27 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 ☒

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:55
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

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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US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:27
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 ☒

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:03
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

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)

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:23
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:02
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

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EAB) (1725)

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:03
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412012

Folder: Safety Call Day 36 (1)

Form: Safety Call

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

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 36 (1)

Form: Continuing

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

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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) _____

US3412012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

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)	10:58 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:58

US3412012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:40

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 OCT 2020 10:13:27
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

05 OCT 2020 07:40:45

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 OCT 2020 11:02:45
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 10:44:09

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 14:47:59

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 08:44:33

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 12:34:33

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 11:44:40

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 07:30:36

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 06:45:58
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 12:13:35
Patient Cloud Open Date & Time	25 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	139 of 3096

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 12:10:35

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 00:31:34

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 13:31:01

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 06:51:57
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 187

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

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

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

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 09:03:59
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 00:23:18

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

26 FEB 2021 08:28:59

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 07:42:32
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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 MAR 2021 16:29:24
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 09:11:05
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

26 MAR 2021 09:13:16

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

13 APR 2021 06:24:37

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

20 APR 2021 10:03:18

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 23:19:31

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 07:23:40

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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°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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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01 APR 2022 00:01

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05 APR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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08 APR 2022 00:01

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12 APR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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15 APR 2022 00:01

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19 APR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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26 APR 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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24 MAY 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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31 MAY 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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07 JUN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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21 JUN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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24 JUN 2022 00:01

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28 JUN 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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05 JUL 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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26 JUL 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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09 AUG 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

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

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23 AUG 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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 <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"/>

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:39:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	04 MAR 2021 11:21:01

US3412012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:25:49

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:25:49

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

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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US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

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)	11:24 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:24
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

25 FEB 2021 11:40

US3412012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 14:57:33

Generated On: 11 Aug 2021 22:39:31

Date of Contact	28 DEC 2020
Time of Contact	13:00
Date and Time of Contact (derived)	28 DEC 2020 13:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	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)

330 of 3096

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	True
---------------------	------

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	True
---------------------	------

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	ND - Not Done
---------------	---------------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 (5)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	95 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 14:57:34

Generated On: 11 Aug 2021 22:39:31

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input 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 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	96 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:34

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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	94 %	
O2 Saturation Units	%	
Temperature	99.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" 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 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 (8)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" 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 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

Date	2 JAN 2021
------	------------

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

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

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

Temperature	99.3 F
-------------	--------

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

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

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

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

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Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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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Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	3 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input 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 28 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

Date	4 JAN 2021
------	------------

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

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

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

Temperature	98.8 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 JAN 2021	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

Date	7 JAN 2021
------	------------

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

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

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

Temperature	99.7 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

Date	8 JAN 2021
------	------------

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

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

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

Temperature	99.4 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 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 28 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 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 28 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 (19)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
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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EAB) (1725)

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 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 28 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 28 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 (24)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

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Form: Symptom Log (24)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
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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EAB) (1725)

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Form: Symptom Log (24)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 (24)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 28 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

Symptom Day

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

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 JAN 2021	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 28 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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 checked="" 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 28 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
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 28 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

	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 28 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Apr 2021 14:57:34

Generated On: 11 Aug 2021 22:39:31

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"/>

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 14:57:33

Generated On: 11 Aug 2021 22:39:31

Date of Visit	28 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	28 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)	1

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:33

Generated On: 11 Aug 2021 22:39:31

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 _____ 06 JAN 2021

End Date _____ 18 JAN 2021

Oxygen Saturation _____ 91 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:33

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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 28 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:33

Generated On: 11 Aug 2021 22:39:31

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

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:33

Generated On: 11 Aug 2021 22:39:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 14:57:36

Generated On: 11 Aug 2021 22:39:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 DEC 2020
Day 5	Yes	01 JAN 2021
Day 7	Yes	03 JAN 2021
Day 9	Yes	05 JAN 2021
Day 14	No	
Day 21	No	
Day 28	Yes	26 JAN 2021

US3412012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	13:13 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 13:13
Height (xxx.x)	168.0 cm
Weight (xxx.x)	117.7 kg
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 DEC 2020

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

US3412012

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 14:57:36

Generated On: 11 Aug 2021 22:39:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 DEC 2020

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:57:32

Generated On: 11 Aug 2021 22:39:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:57:32

Generated On: 11 Aug 2021 22:39:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 12:36
Height (xxx.x)	168.0 cm
Weight (xxx.x)	117.3 kg
Temperature (xxx.x)	36.8 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:57:32

Generated On: 11 Aug 2021 22:39:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3412012

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 14:57:32

Generated On: 11 Aug 2021 22:39:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 JAN 2021

US3412012

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412012

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Date of updated informed consent (<i>dd MMM yyyy</i>)	26 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>)	26 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

US3412012

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Height	168.5 cm
Weight	111.8 kg
BMI (xxx.x)	39.37694

US3412012

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Height	168.5 cm
Weight	111.8 kg
BMI (xxx.x)	39.37694
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)	11:24 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:24
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Height	168.5 cm
Weight	111.8 kg
BMI (xxx.x)	39.37694
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)	13:21 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3412012

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was the pregnancy test performed? Yes ☒ No ☐

Date of test (dd MMM yyyy) 25 FEB 2021

Test performed Urine ☒ Serum ☐

Result Positive ☐ Negative ☒

Was FSH sample collected? Yes ☐ No ☒

Collection date

Collection time

Collection date and time (derived)

US3412012

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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) 12:50 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 12:50

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

US3412012

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	26 JAN 2021 12:45

US3412012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00 - 23:59)

12:47

Collection Date and Time (derived)

26 JAN 2021 12:47

US3412012

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:25:49

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:25:49

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID OLD29

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3412012

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

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)

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3412012

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:51:55

Generated On: 11 Aug 2021 22:39:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412012

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412012

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3412012

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

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.

US3412012

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 16 Apr 2021 13:51:55

Generated On: 11 Aug 2021 22:39:31

Visit Date	25 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:38

Generated On: 11 Aug 2021 22:39:31

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)	11:52 (24 HR)
Collection date and time (derived)	25 FEB 2021 11:52

US3412012

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:18:20

Generated On: 11 Aug 2021 22:39:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

AEID

Adverse event

BILATERAL BREAST SORENESS

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)

01 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

AEID	USA-US061-2021-MRNA-1273-P30 1000002
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)	25 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

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	

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

SUBJECT'S DAUGHTER HAD COVID-19. SUBJECT STARTED EXPERIENCING SYMPTOMS OF COUGH, FEVER, CHILLS ON 25DEC2020. SHE NO LONGER HAS A FEVER BUT COMPLAINS OF MILD COUGH, LOSS OF SMELL, AND FAITGUE. ON 29DEC2020 SUBJECT REPORTED FEELING WORSE. ON 03JAN2021 SUBJECT STATED THEY HAD ONE TIME DIARRHEA BUT WAS FEELING GREAT. ON 04JAN SUBJECT IS FEELING BETTER AND ONLY HAS EXPERIENCED MILD SHORTNESS OF BREATH AND MILD FATIGUE, ONLY MILD FATIGUE ON 05JAN2021. SUBJECT EXPERIENCED MILD-MODERATE SYMPTOMS UNTIL ALL SYMPTOMS RESOLVED 19JAN2021.

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)	

US3412012

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

AEID

Adverse event

PRE DIABETES

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 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 14:57:31

Generated On: 11 Aug 2021 22:39:31

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" 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) _____	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:30:29

Generated On: 11 Aug 2021 22:39:31

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication MYALGIAS, ARTHALGIAS
GENERALIZED (SOLICITED)

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

4 TABLETS FOR ONE DAY.

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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)		01 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication SUBONXONE

Prophylaxis Yes ☐
No ☒

Indication OPIOID ABUSE REMISSION

Dose per administration 8

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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EAB) (1725)

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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 2007	
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"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication LOWER EXTREMITY EDEMA

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication XFACTOR PLUS MULTIVITAMIN

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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 JAN 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"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication VITAL BIOME

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

Dose per administration 1-2

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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 JAN 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"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication BIOTIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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 APR 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 (9)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SOLICITED MYALGIA,
ARTHRALGIAS

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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)	1 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication OBESITY / WEIGHT LOSS /
BORDER LINE DIABETIC

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	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)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration UNK

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:12:07

Generated On: 11 Aug 2021 22:39:31

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2018
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"/>

US3412012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 14:57:32

Generated On: 11 Aug 2021 22:39:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412012

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:39:31

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

US3412012

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:39:31

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 ☐

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

SAEID	USA-US061-2021-MRNA-1273-P301000002
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

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

SAEID	USA-US061-2021-MRNA-1273-P301000002
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)	07/JAN/2021 14:28
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

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

SAEID	USA-US061-2021-MRNA-1273-P301000002
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)	02/FEB/2021 08:50
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

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 14:57:37

Generated On: 11 Aug 2021 22:39:31

SAEID	USA-US061-2021-MRNA-1273-P301000002
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)	25/MAR/2021 15:48
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

Audit

US3412012 (Prod: New Horizons Clinical Research)

US3412012

Form: Participant Creation

Generated On: 11 Aug 2021 22:39:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'US3412012'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:39:25

US3412012

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 16:49:49
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:39:26

US3412012

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Clinic (Clinic)'	(b) (4)	29 Jul 2020 16:49:49

US3412012

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'SCRN'	System	29 Jul 2020 16:49:49

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:39:27

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '46'	(b) (4) Zachary Eardley (b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'YEARS'	System	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '46'	System	29 Jul 2020 16:50:26

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Female (F)'	(b) (4)	29 Jul 2020 16:50:03
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Zachary Eardley (b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'I'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) Zachary Eardley (b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4)	29 Jul 2020 16:50:03
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:39:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4)	29 Jul 2020 16:50:03

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 Jul 2020'	(b) (4)	29 Jul 2020 16:50:26
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jul 2020'	System	29 Jul 2020 16:50:26

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2020'	System	29 Jul 2020 16:50:26

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Amendment 1 (1)'	(b) (4)	29 Jul 2020 16:50:26
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 16:50:26

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4)	29 Jul 2020 16:50:26
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4)	29 Jul 2020 16:50:26
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4)	29 Jul 2020 16:50:26
	Zachary Eardley (b) (4)	

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:39:26

US3412012

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:39:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'I'	System	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:39:31

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:39:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:03

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 07:31:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 07:31:47
Data point term sent to Coder	System	14 Sep 2020 14:22:38
User closed query 'For coding purposes, please enter the location for CHRONIC SWELLING in order that the term may be coded accurately and to the appropriate body site, or specify if generalized. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	System	14 Sep 2020 14:22:03
Query 'For coding purposes, please enter the location for CHRONIC SWELLING in order that the term may be coded accurately and to the appropriate body site, or specify if generalized. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' answered with 'OK' (Site from System).	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:22:03
User entered 'CHRONIC SWELLING LOWER EXTREMITIES NON PITTING EDEMA' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:21:48
User opened query 'For coding purposes, please enter the location for CHRONIC SWELLING in order that the term may be coded accurately and to the appropriate body site, or specify if generalized. Please make your changes to the reported term accordingly in the diagnosis field to enable coding.' (Site from System).	Coder Import (b) (4)	04 Aug 2020 16:09:56
Data point term sent to Coder	System	04 Aug 2020 15:07:22
User entered 'Chronic Swelling'	(b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2017'	System	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2017'	System	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:06:58

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 10:38:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 10:38:36
Data point term sent to Coder	System	14 Sep 2020 14:22:38
Coding entries removed.	Mylene Asmar-Rios	14 Sep 2020 14:22:22
User entered 'NAUSEA ASSOCIATED WITH MEDS' reason for change: Data Entry Error	Mylene Asmar-Rios	14 Sep 2020 14:22:22
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 15:07:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 15:07:55
Data point term sent to Coder	System	04 Aug 2020 15:07:24
User entered 'Nausea'	(b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2007'	System	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2007'	System	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:07:13

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug use disorder, LLT: Opioid use disorder - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 11:24:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 11:24:16
Data point term sent to Coder	System	04 Aug 2020 15:08:24
User entered 'Opiod use disorder remission'	(b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2007'	System	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2007'	System	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	04 Aug 2020 15:07:45

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:10:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:10:31
Data point term sent to Coder	System	05 Oct 2020 19:09:50
User entered 'Anemia'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2017'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2017'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2017'	System	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2017'	System	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2017'	System	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2017'	System	05 Oct 2020 19:09:23

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
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 Oct 2020 19:10:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:10:31
Data point term sent to Coder	System	05 Oct 2020 19:09:50
User entered 'anxiety'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45
	(b) (4)	

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2010'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2016'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2010'	System	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2010'	System	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2016'	System	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2016'	System	05 Oct 2020 19:09:45

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
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 Oct 2020 19:11:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:11:19
Data point term sent to Coder	System	05 Oct 2020 19:10:50
User entered 'depression'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2010'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2016'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2010'	System	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2010'	System	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2016'	System	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2016'	System	05 Oct 2020 19:10:04

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis A, LLT: Hepatitis A - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:21
Data point term sent to Coder	System	05 Oct 2020 19:11:53
User entered 'hepatitis A'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 1986'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 1986'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 1986'	System	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '1986'	System	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 1986'	System	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '1986'	System	05 Oct 2020 19:10:54

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:22
Data point term sent to Coder	System	05 Oct 2020 19:11:53
User entered 'endometriosis'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 1990'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'un UNK 2016'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 1990'	System	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '1990'	System	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jan 2016'	System	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2016'	System	05 Oct 2020 19:11:22

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 14:07:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Nov 2020 14:07:50
Data point term sent to Coder	System	30 Nov 2020 14:06:35
User entered 'OBESITY'	Melissa Fuson (b) (4)	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 Jul 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Nov 2020 14:06:52
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	30 Nov 2020 14:06:52
User entered '1'	(b) (4)	
	Melissa Fuson (b) (4)	30 Nov 2020 14:06:28
	(b) (4)	

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	Melissa Fuson (b) (4)	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'Jul 2020'	System	30 Nov 2020 14:06:52
User entered empty.	System	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '2020'	System	30 Nov 2020 14:06:52
User entered empty.	System	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:39:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	30 Nov 2020 14:06:28

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '12:05'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered '29 Jul 2020 12:05'	System	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '168.1' cm	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52
DataPoint set to visible.	System	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '117.7' kg	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52
DataPoint set to visible.	System	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
Amendment Manager: User entered '41.65250'	System	16 Sep 2020 23:38:04
User entered '41.7'	System	04 Aug 2020 15:11:52
DataPoint set to visible.	System	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'kg/m2'	System	04 Aug 2020 15:11:52
DataPoint set to visible.	System	29 Jul 2020 17:46:53

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 18:38:26
User entered '36.7' C	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 04:22:44
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:38:33
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 18:38:26
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:38:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 18:38:26
User entered '74'	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'bpm'	System	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 18:38:26
User entered '14'	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'breaths/min'	System	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 18:38:26
User entered '102'	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'mmHg'	System	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 18:38:26
User entered '62'	(b) (4), (b) (6)	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered 'mmHg'	System	04 Aug 2020 15:11:52

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55

US3412012

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55

US3412012

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:00

US3412012

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
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 13:35:05
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 15:30:04
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 15:12:00

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:39:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:08

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User closed query 'Per CDM, Was FSH sample collected is recorded as 'No'. However Collection date and time are provided. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 08:17:17
Query 'Per CDM, Was FSH sample collected is recorded as 'No'. However Collection date and time are provided. Please review and update accordingly. ' answered with 'NO' (Site from DM).	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:23:51
User opened query 'Per CDM, Was FSH sample collected is recorded as 'No'. However Collection date and time are provided. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 19:44:42
User entered 'No (N)'		04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty; reason for change Data Entry Error	(b) (4)	14 Sep 2020 14:23:40
User entered '29 Jul 2020'	Mylene Asmar-Rios (b) (4)	04 Aug 2020 15:12:36
	(b) (4), (b) (6)	

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty; reason for change Data Entry Error	(b) (4)	14 Sep 2020 14:23:40
User entered '12:11'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User entered empty.	System	14 Sep 2020 14:23:40
User entered '29 Jul 2020 12:11'	System	04 Aug 2020 15:12:36

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

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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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

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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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

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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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 14:25:53
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'LIVES WITH CONSTRUCTION WORKER AND RESTURANT EMPLOYEE' reason for change: Data Entry Error	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:25:53
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

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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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

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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 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '0' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 14:25:53
User entered '1'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:39:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:28:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty; reason for change Data Entry Error	(b) (4)	14 Sep 2020 14:25:53
User entered 'Lives in high risk county and with essential workers'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 15:13:29

US3412012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 16:50:58
	Zachary Eardley (b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020'	(b) (4)	29 Jul 2020 16:50:58
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Clinic (Clinic)'	(b) (4)	29 Jul 2020 16:50:58

US3412012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'VISIT1'	System	29 Jul 2020 16:50:58

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:49:19

US3412012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:14:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:14:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 16:49:19
User entered '142256' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:49:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:49:19

US3412012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

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)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4)	29 Jul 2020 16:51:33
	Zachary Eardley (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

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)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4)	29 Jul 2020 16:51:33
	Zachary Eardley (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 16:51:33
	Zachary Eardley (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4)	29 Jul 2020 16:51:33

US3412012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:39:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4)	29 Jul 2020 16:51:33
	Zachary Eardley (b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Pre-Dose (PREDOSE)'		04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered 'No (N)'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '12:05' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '29 Jul 2020 12:05'	System	19 Aug 2020 18:40:06
User entered empty.	System	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '36.7' C reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '74' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Aug 2020 15:14:27
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'bpm'	System	19 Aug 2020 18:40:06
User entered empty.	System	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '14' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Aug 2020 15:14:27
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'breaths/min'	System	19 Aug 2020 18:40:06
User entered empty.	System	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '102' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	19 Aug 2020 18:40:06
User entered empty.	System	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '62' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 18:40:06
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Aug 2020 15:14:27
	(b) (4), (b) (6)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	19 Aug 2020 18:40:06
User entered empty.	System	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
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 15:59:19
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 15:00:45
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).		04 Aug 2020 15:14:27
User entered '13:41'	(b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '29 Jul 2020 13:41'	System	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '72'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'bpm'	System	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'breaths/min'	System	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '112'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '68'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	04 Aug 2020 15:14:27

US3412012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:32

US3412012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:32

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 05:46:02
Query 'Per CDM: Please provide a response for Was FSH sample collected?' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:47:36
Signature has been broken.	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:47:30
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:47:30
User opened query 'Per CDM: Please provide a response for Was FSH sample collected?' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:04:01
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	04 Aug 2020 15:14:37

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4)	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4)	29 Jul 2020 17:47:51
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

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)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4)	29 Jul 2020 17:47:51
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020'	(b) (4)	29 Jul 2020 17:47:51
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '13:10'	(b) (4)	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '29 Jul 2020 13:10'	System	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4)	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'ONCE'	System	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 17:47:51

US3412012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:15:09

US3412012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:15:09

US3412012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '12:40'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:15:09

US3412012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '29 Jul 2020 12:40'	System	04 Aug 2020 15:15:09

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '12:35'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '29 Jul 2020 12:35'	System	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	04 Aug 2020 15:14:56

US3412012

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:14:40

US3412012

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	04 Aug 2020 15:14:40

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:49:43', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf2dceba-1307-44e1-bc3a-366fd1b5e8c7'	System	29 Jul 2020 17:50:06
User entered 'Yes (Y)'	System	29 Jul 2020 17:50:06

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:49:50', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf2dceba-1307-44e1-bc3a-366fd1b5e8c7'	System	29 Jul 2020 17:50:06
User entered '97.7'	System	29 Jul 2020 17:50:06

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:49:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf2dceba-1307-44e1-bc3a-366fd1b5e8c7'	System	29 Jul 2020 17:50:06
User entered 'No (N)'	System	29 Jul 2020 17:50:06

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf2dceba-1307-44e1-bc3a-366fd1b5e8c7'	System	29 Jul 2020 17:50:06
User entered '29 Jul 2020 13:50'	System	29 Jul 2020 17:50:06

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 13:30'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:06:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b4a85581-fd09-4962-81d8-be20111abdb0'	System	30 Jul 2020 01:07:10
User entered 'Yes (Y)'	System	30 Jul 2020 01:07:10

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:06:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b4a85581-fd09-4962-81d8-be20111abdb0'	System	30 Jul 2020 01:07:10
User entered '97.9'	System	30 Jul 2020 01:07:10

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:07:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b4a85581-fd09-4962-81d8-be20111abdb0'	System	30 Jul 2020 01:07:10
User entered 'No (N)'	System	30 Jul 2020 01:07:10

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:07:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b4a85581-fd09-4962-81d8-be20111abdb0'	System	30 Jul 2020 01:07:10
User entered '29 Jul 2020 21:07'	System	30 Jul 2020 01:07:10

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:55'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 2'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:27:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '61b69970-0a53-44cc-8f62-bac6edfc39be'	System	31 Jul 2020 01:28:07
User entered 'Yes (Y)'	System	31 Jul 2020 01:28:07

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:27:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '61b69970-0a53-44cc-8f62-bac6edfc39be'	System	31 Jul 2020 01:28:07
User entered '98.6'	System	31 Jul 2020 01:28:07

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:27:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '61b69970-0a53-44cc-8f62-bac6edfc39be'	System	31 Jul 2020 01:28:07
User entered 'No (N)'	System	31 Jul 2020 01:28:07

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:28:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '61b69970-0a53-44cc-8f62-bac6edfc39be'	System	31 Jul 2020 01:28:07
User entered '30 Jul 2020 21:28'	System	31 Jul 2020 01:28:07

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 3'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:51:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '87042444-0944-4d60-a463-e5ed9590dae5'	System	01 Aug 2020 00:51:43
User entered 'Yes (Y)'	System	01 Aug 2020 00:51:43

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:51:34', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '87042444-0944-4d60-a463-e5ed9590dae5'	System	01 Aug 2020 00:51:43
User entered '98.0'	System	01 Aug 2020 00:51:43

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:51:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '87042444-0944-4d60-a463-e5ed9590dae5'	System	01 Aug 2020 00:51:43
User entered 'No (N)'	System	01 Aug 2020 00:51:43

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:51:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '87042444-0944-4d60-a463-e5ed9590dae5'	System	01 Aug 2020 00:51:43
User entered '31 Jul 2020 20:51'	System	01 Aug 2020 00:51:43

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 4'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered 'Yes (Y)'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:14', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered '98.3'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered 'Yes (Y)'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Query 'Per CDM RQ: Response noted as 'Subject contacted and concomitant medication page updated' to treat pain or fever however Prior/Concomitant Medication page is not completed. Kindly reconcile and update the data in Concomitant and Dairy Dose form as appropriate else clarify in query response. ' canceled (Site from DM).		28 Aug 2020 09:59:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		17 Aug 2020 15:59:42
User opened query 'Per CDM RQ: Response noted as 'Subject contacted and concomitant medication page updated' to treat pain or fever however Prior/Concomitant Medication page is not completed. Kindly reconcile and update the data in Concomitant and Dairy Dose form as appropriate else clarify in query response. ' (Site from DM).		10 Aug 2020 10:22:34
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject contacted and concomitant medication page updated. ' (Site from System).	Zachary Eardley (b) (4)	05 Aug 2020 22:44:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	02 Aug 2020 01:17:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered '1'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered '0'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:17:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ddf6eb11-204e-46c0-983c-c4800523eae5'	System	02 Aug 2020 01:17:42
User entered '01 Aug 2020 21:17'	System	02 Aug 2020 01:17:42

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 5'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3a1e1465-a2c6-459f-8cdf-bb41e12f4da0'	System	03 Aug 2020 10:16:46
User entered 'Yes (Y)'	System	03 Aug 2020 10:16:46

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:37', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3a1e1465-a2c6-459f-8cdf-bb41e12f4da0'	System	03 Aug 2020 10:16:46
User entered '97.0'	System	03 Aug 2020 10:16:46

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3a1e1465-a2c6-459f-8cdf-bb41e12f4da0'	System	03 Aug 2020 10:16:46
User entered 'No (N)'	System	03 Aug 2020 10:16:46

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3a1e1465-a2c6-459f-8cdf-bb41e12f4da0'	System	03 Aug 2020 10:16:46
User entered '03 Aug 2020 06:16'	System	03 Aug 2020 10:16:46

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 6'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:19:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a7dbdf0e-9df0-4fda-95f5-2f6d4c601488'	System	04 Aug 2020 01:20:33
User entered 'Yes (Y)'	System	04 Aug 2020 01:20:33

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:19:59', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a7dbdf0e-9df0-4fda-95f5-2f6d4c601488'	System	04 Aug 2020 01:20:33
User entered '97.1'	System	04 Aug 2020 01:20:33

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a7dbdf0e-9df0-4fda-95f5-2f6d4c601488'	System	04 Aug 2020 01:20:33
User entered 'No (N)'	System	04 Aug 2020 01:20:33

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a7dbdf0e-9df0-4fda-95f5-2f6d4c601488'	System	04 Aug 2020 01:20:33
User entered '03 Aug 2020 21:20'	System	04 Aug 2020 01:20:33

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 7'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:47', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '5d79a975-fe57-4104-833c-8b41805350df'	System	05 Aug 2020 01:01:03
User entered 'Yes (Y)'	System	05 Aug 2020 01:01:03

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '5d79a975-fe57-4104-833c-8b41805350df'	System	05 Aug 2020 01:01:03
User entered '97.9'	System	05 Aug 2020 01:01:03

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:54', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '5d79a975-fe57-4104-833c-8b41805350df'	System	05 Aug 2020 01:01:03
User entered 'No (N)'	System	05 Aug 2020 01:01:03

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '5d79a975-fe57-4104-833c-8b41805350df'	System	05 Aug 2020 01:01:03
User entered '04 Aug 2020 21:00'	System	05 Aug 2020 01:01:03

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:19', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6e235245-cb78-403c-b6a3-dc8095e9c4fc'	System	29 Jul 2020 17:50:51
User entered 'None (1)'	System	29 Jul 2020 17:50:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6e235245-cb78-403c-b6a3-dc8095e9c4fc'	System	29 Jul 2020 17:50:51
User entered 'No (N)'	System	29 Jul 2020 17:50:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6e235245-cb78-403c-b6a3-dc8095e9c4fc'	System	29 Jul 2020 17:50:51
User entered 'No (N)'	System	29 Jul 2020 17:50:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6e235245-cb78-403c-b6a3-dc8095e9c4fc'	System	29 Jul 2020 17:50:51
User entered 'None (1)'	System	29 Jul 2020 17:50:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:50:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6e235245-cb78-403c-b6a3-dc8095e9c4fc'	System	29 Jul 2020 17:50:51
User entered '29 Jul 2020 13:50'	System	29 Jul 2020 17:50:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 13:30'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:07:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '68661da3-9f5f-4bf9-8d09-1a53c6a0bd80'	System	30 Jul 2020 01:08:12
User entered 'None (1)'	System	30 Jul 2020 01:08:12

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:07:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '68661da3-9f5f-4bf9-8d09-1a53c6a0bd80'	System	30 Jul 2020 01:08:12
User entered 'No (N)'	System	30 Jul 2020 01:08:12

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:07:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '68661da3-9f5f-4bf9-8d09-1a53c6a0bd80'	System	30 Jul 2020 01:08:12
User entered 'No (N)'	System	30 Jul 2020 01:08:12

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '68661da3-9f5f-4bf9-8d09-1a53c6a0bd80'	System	30 Jul 2020 01:08:12
User entered 'None (1)'	System	30 Jul 2020 01:08:12

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '68661da3-9f5f-4bf9-8d09-1a53c6a0bd80'	System	30 Jul 2020 01:08:12
User entered '29 Jul 2020 21:08'	System	30 Jul 2020 01:08:12

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:55'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 2'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e4ca9e16-d802-4f51-b6c4-4845149bdb21'	System	31 Jul 2020 01:29:53
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 01:29:53

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e4ca9e16-d802-4f51-b6c4-4845149bdb21'	System	31 Jul 2020 01:29:53
User entered 'No (N)'	System	31 Jul 2020 01:29:53

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e4ca9e16-d802-4f51-b6c4-4845149bdb21'	System	31 Jul 2020 01:29:53
User entered 'No (N)'	System	31 Jul 2020 01:29:53

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e4ca9e16-d802-4f51-b6c4-4845149bdb21'	System	31 Jul 2020 01:29:53
User entered 'None (1)'	System	31 Jul 2020 01:29:53

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e4ca9e16-d802-4f51-b6c4-4845149bdb21'	System	31 Jul 2020 01:29:53
User entered '30 Jul 2020 21:29'	System	31 Jul 2020 01:29:53

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 3'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:52:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3f5f1fb8-30b4-43ee-b152-fb248c31606a'	System	01 Aug 2020 00:52:45
User entered 'None (1)'	System	01 Aug 2020 00:52:45

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:52:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3f5f1fb8-30b4-43ee-b152-fb248c31606a'	System	01 Aug 2020 00:52:45
User entered 'No (N)'	System	01 Aug 2020 00:52:45

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:52:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3f5f1fb8-30b4-43ee-b152-fb248c31606a'	System	01 Aug 2020 00:52:45
User entered 'No (N)'	System	01 Aug 2020 00:52:45

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:52:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3f5f1fb8-30b4-43ee-b152-fb248c31606a'	System	01 Aug 2020 00:52:45
User entered 'None (1)'	System	01 Aug 2020 00:52:45

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:52:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3f5f1fb8-30b4-43ee-b152-fb248c31606a'	System	01 Aug 2020 00:52:45
User entered '31 Jul 2020 20:52'	System	01 Aug 2020 00:52:45

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 4'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '74bb1ef2-0d1a-4f7d-96be-da2a43af26fa'	System	02 Aug 2020 01:18:20
User entered 'None (1)'	System	02 Aug 2020 01:18:20

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '74bb1ef2-0d1a-4f7d-96be-da2a43af26fa'	System	02 Aug 2020 01:18:20
User entered 'No (N)'	System	02 Aug 2020 01:18:20

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '74bb1ef2-0d1a-4f7d-96be-da2a43af26fa'	System	02 Aug 2020 01:18:20
User entered 'No (N)'	System	02 Aug 2020 01:18:20

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:13', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '74bb1ef2-0d1a-4f7d-96be-da2a43af26fa'	System	02 Aug 2020 01:18:20
User entered 'None (1)'	System	02 Aug 2020 01:18:20

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:17', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '74bb1ef2-0d1a-4f7d-96be-da2a43af26fa'	System	02 Aug 2020 01:18:20
User entered '01 Aug 2020 21:18'	System	02 Aug 2020 01:18:20

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 5'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fa49d1fc-685a-45f9-8878-53ee398205fb'	System	03 Aug 2020 10:17:08
User entered 'None (1)'	System	03 Aug 2020 10:17:08

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fa49d1fc-685a-45f9-8878-53ee398205fb'	System	03 Aug 2020 10:17:08
User entered 'No (N)'	System	03 Aug 2020 10:17:08

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:16:57', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fa49d1fc-685a-45f9-8878-53ee398205fb'	System	03 Aug 2020 10:17:08
User entered 'No (N)'	System	03 Aug 2020 10:17:08

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:01', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fa49d1fc-685a-45f9-8878-53ee398205fb'	System	03 Aug 2020 10:17:08
User entered 'None (1)'	System	03 Aug 2020 10:17:08

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fa49d1fc-685a-45f9-8878-53ee398205fb'	System	03 Aug 2020 10:17:08
User entered '03 Aug 2020 06:17'	System	03 Aug 2020 10:17:08

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 6'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:20', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75a60e4a-7cb1-4341-b895-b11e33518c66'	System	04 Aug 2020 01:20:39
User entered 'None (1)'	System	04 Aug 2020 01:20:39

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75a60e4a-7cb1-4341-b895-b11e33518c66'	System	04 Aug 2020 01:20:39
User entered 'No (N)'	System	04 Aug 2020 01:20:39

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75a60e4a-7cb1-4341-b895-b11e33518c66'	System	04 Aug 2020 01:20:39
User entered 'No (N)'	System	04 Aug 2020 01:20:39

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75a60e4a-7cb1-4341-b895-b11e33518c66'	System	04 Aug 2020 01:20:39
User entered 'None (1)'	System	04 Aug 2020 01:20:39

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75a60e4a-7cb1-4341-b895-b11e33518c66'	System	04 Aug 2020 01:20:39
User entered '03 Aug 2020 21:20'	System	04 Aug 2020 01:20:39

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 7'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T20:59:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf9d5216-aeb8-4a59-83f5-af19b99377f6'	System	05 Aug 2020 01:00:06
User entered 'None (1)'	System	05 Aug 2020 01:00:06

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T20:59:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf9d5216-aeb8-4a59-83f5-af19b99377f6'	System	05 Aug 2020 01:00:06
User entered 'No (N)'	System	05 Aug 2020 01:00:06

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T20:59:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf9d5216-aeb8-4a59-83f5-af19b99377f6'	System	05 Aug 2020 01:00:06
User entered 'No (N)'	System	05 Aug 2020 01:00:06

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T20:59:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf9d5216-aeb8-4a59-83f5-af19b99377f6'	System	05 Aug 2020 01:00:06
User entered 'None (1)'	System	05 Aug 2020 01:00:06

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:01', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'bf9d5216-aeb8-4a59-83f5-af19b99377f6'	System	05 Aug 2020 01:00:06
User entered '04 Aug 2020 21:00'	System	05 Aug 2020 01:00:06

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:16', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:35', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'None (0)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered 'No (N)'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T13:51:57', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '38bb767b-9053-42f4-9d25-a77c4b756dce'	System	29 Jul 2020 17:52:01
User entered '29 Jul 2020 13:51'	System	29 Jul 2020 17:52:01

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 13:30'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:20', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'None (0)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:08:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered 'No (N)'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-29T21:09:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0a27f608-90c2-4867-af8f-1ed778474702'	System	30 Jul 2020 01:09:02
User entered '29 Jul 2020 21:09'	System	30 Jul 2020 01:09:02

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Jul 2020 16:55'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 2'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:54', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:29:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:30:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:30:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:30:07', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'None (0)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:30:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered 'No (N)'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-30T21:30:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a41de965-d1d2-41ca-99d1-eccb7c8e303d'	System	31 Jul 2020 01:30:35
User entered '30 Jul 2020 21:30'	System	31 Jul 2020 01:30:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 3'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'No interference with activity (1)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'None (0)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:16', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'None (0)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'None (0)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'None (0)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'None (0)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:37', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered 'No (N)'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-07-31T20:53:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '75efdd7a-f9ed-4d32-80b7-1f6f3ded3580'	System	01 Aug 2020 00:53:48
User entered '31 Jul 2020 20:53'	System	01 Aug 2020 00:53:48

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 4'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'None (0)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'Some interference with activity (2)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'No interference with activity (1)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'Some interference with activity (2)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'None (0)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'None (0)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered 'No (N)'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-01T21:18:50', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '546b037a-d42c-4288-862c-dc05255b81e5'	System	02 Aug 2020 01:18:55
User entered '01 Aug 2020 21:18'	System	02 Aug 2020 01:18:55

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 5'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:07', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'None (0)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:16', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'None (0)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'None (0)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'No interference with activity (1)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:31', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'None (0)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'None (0)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered 'No (N)'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T06:17:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '246d923b-d549-4269-aec2-1ca6c4dda486'	System	03 Aug 2020 10:17:54
User entered '03 Aug 2020 06:17'	System	03 Aug 2020 10:17:54

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 6'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'None (0)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered 'No (N)'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-03T21:20:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '300ab6b2-23ee-45e3-9b75-b919410200e8'	System	04 Aug 2020 01:20:52
User entered '03 Aug 2020 21:20'	System	04 Aug 2020 01:20:52

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 7'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:07', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'None (0)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:09', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'None (0)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:13', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'None (0)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'No interference with activity (1)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'None (0)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'None (0)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered 'No (N)'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-04T21:00:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'fc7ff2d0-3e8e-46ed-ade6-68e95996e72b'	System	05 Aug 2020 01:00:35
User entered '04 Aug 2020 21:00'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	05 Aug 2020 01:00:35
User entered 'Day 8'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-05T21:01:43', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c1829b43-e466-4c80-bcd3-5c3477a2eeb8'	System	06 Aug 2020 01:01:52
User entered 'None (0)'	System	06 Aug 2020 01:01:52

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-05T21:01:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c1829b43-e466-4c80-bcd3-5c3477a2eeb8'	System	06 Aug 2020 01:01:52
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 01:01:52

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '05 Aug 2020 12:00'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	05 Aug 2020 01:00:35
User entered 'Day 8'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-05T21:01:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '55b554c1-140d-4871-8e2c-05a64ac4de30'	System	06 Aug 2020 01:01:58
User entered 'No (N)'	System	06 Aug 2020 01:01:58

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-05T21:01:55', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '55b554c1-140d-4871-8e2c-05a64ac4de30'	System	06 Aug 2020 01:01:58
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 01:01:58

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '05 Aug 2020 12:00'	System	05 Aug 2020 01:00:35

US3412012

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 01:00:35

US3412012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4)	11 Aug 2020 14:02:52
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered '05 Aug 2020'	(b) (4)	11 Aug 2020 14:02:52
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	11 Aug 2020 14:02:52
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered empty.	(b) (4)	11 Aug 2020 14:02:52
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:09
User entered 'Yes (Y)'	(b) (4)	11 Aug 2020 14:02:58
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	11 Aug 2020 14:02:58

US3412012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4)	12 Aug 2020 22:55:46
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered '12 Aug 2020'	(b) (4)	12 Aug 2020 22:55:46
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	12 Aug 2020 22:55:46

US3412012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered empty.	(b) (4)	12 Aug 2020 22:55:46
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4)	12 Aug 2020 22:55:50
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User entered 'I'	System	12 Aug 2020 22:55:50

US3412012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4)	26 Aug 2020 15:29:45
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered '19 Aug 2020'	(b) (4)	26 Aug 2020 15:29:45
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	26 Aug 2020 15:29:45

US3412012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered empty.	(b) (4)	26 Aug 2020 15:29:45
	Zachary Eardley (b) (4)	

US3412012

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4)	26 Aug 2020 15:29:50

US3412012

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	26 Aug 2020 15:29:50

US3412012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4)	26 Aug 2020 15:30:04

US3412012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4)	26 Aug 2020 15:30:04
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Clinic (Clinic)'	(b) (4)	26 Aug 2020 15:30:04

US3412012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'VISIT2'	System	26 Aug 2020 15:30:04

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '10:26'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '26 Aug 2020 10:26'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '36.7' C	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Oral (Oral)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '50'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'bpm'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '16'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'breaths/min'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '112'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '72'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '11:56'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '26 Aug 2020 11:56'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '97.6' F	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Oral (Oral)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '60'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'bpm'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '15'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'breaths/min'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '120'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '78'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	14 Sep 2020 14:55:40

US3412012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:04

US3412012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:04

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Urine (URINE)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Negative (NEGATIVE)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	14 Sep 2020 14:56:30

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4)	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4)	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

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)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4)	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4)	26 Aug 2020 15:30:27
	Zachary Eardley (b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '11:20'	(b) (4)	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '26 Aug 2020 11:20'	System	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Zachary Eardley (b) (4)	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'ONCE'	System	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:30:27

US3412012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:11

US3412012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:11
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '10:55'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:11
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '26 Aug 2020 10:55'	System	14 Sep 2020 14:57:11

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '10:50'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '26 Aug 2020 10:50'	System	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:57:48
	(b) (4)	

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	14 Sep 2020 14:57:48

US3412012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:52:52

US3412012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '1'	System	02 Sep 2020 15:52:52

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:00:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3e6183d8-8849-4659-8488-971aacc670e4'	System	26 Aug 2020 16:01:43
User entered 'Yes (Y)'	System	26 Aug 2020 16:01:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3e6183d8-8849-4659-8488-971aacc670e4'	System	26 Aug 2020 16:01:43
User entered '97.6'	System	26 Aug 2020 16:01:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3e6183d8-8849-4659-8488-971aacc670e4'	System	26 Aug 2020 16:01:43
User entered 'No (N)'	System	26 Aug 2020 16:01:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:12', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3e6183d8-8849-4659-8488-971aacc670e4'	System	26 Aug 2020 16:01:43
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:01:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 11:40'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 14:10'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:33:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f47fe6a1-5882-4843-90d3-7dc3adf70ddb'	System	27 Aug 2020 01:33:57
User entered 'Yes (Y)'	System	27 Aug 2020 01:33:57

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:33:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f47fe6a1-5882-4843-90d3-7dc3adf70ddb'	System	27 Aug 2020 01:33:57
User entered '96.5'	System	27 Aug 2020 01:33:57

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:33:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f47fe6a1-5882-4843-90d3-7dc3adf70ddb'	System	27 Aug 2020 01:33:57
User entered 'No (N)'	System	27 Aug 2020 01:33:57

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:33:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f47fe6a1-5882-4843-90d3-7dc3adf70ddb'	System	27 Aug 2020 01:33:57
User entered '26 Aug 2020 21:33'	System	27 Aug 2020 01:33:57

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 15:05'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 2'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	System	28 Aug 2020 02:57:34
User entered 'Yes (Y)'	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:57:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	System	28 Aug 2020 02:57:34
User entered '98.0'	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:57:14', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	System	28 Aug 2020 02:57:34
User entered 'Yes (Y)'	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED ' (Site from System).		12 Oct 2020 11:02:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	30 Sep 2020 17:23:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:57:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	(b) (4)	
User entered '1'	System	28 Aug 2020 02:57:34
	System	28 Aug 2020 02:57:34
	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:57:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	System	28 Aug 2020 02:57:34
User entered '0'	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:57:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'e3b7ade5-b522-4b7a-9228-c8108645f566'	System	28 Aug 2020 02:57:34
User entered '27 Aug 2020 22:57'	System	28 Aug 2020 02:57:34

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 3'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:28:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd19b5f2f-6c6d-4bee-a4a9-9c606486fe08'	System	29 Aug 2020 01:28:37
User entered 'Yes (Y)'	System	29 Aug 2020 01:28:37

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:28:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd19b5f2f-6c6d-4bee-a4a9-9c606486fe08'	System	29 Aug 2020 01:28:37
User entered '97.8'	System	29 Aug 2020 01:28:37

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:28:31', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd19b5f2f-6c6d-4bee-a4a9-9c606486fe08'	System	29 Aug 2020 01:28:37
User entered 'No (N)'	System	29 Aug 2020 01:28:37

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:28:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd19b5f2f-6c6d-4bee-a4a9-9c606486fe08'	System	29 Aug 2020 01:28:37
User entered '28 Aug 2020 21:28'	System	29 Aug 2020 01:28:37

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 4'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	System	30 Aug 2020 01:04:29
User entered 'Yes (Y)'	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	System	30 Aug 2020 01:04:29
User entered '97.9'	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	System	30 Aug 2020 01:04:29
User entered 'Yes (Y)'	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'SUBJECT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	12 Oct 2020 11:03:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	30 Sep 2020 17:24:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	(b) (4)	
User entered '1'	System	30 Aug 2020 01:04:29
	System	30 Aug 2020 01:04:29
	System	30 Aug 2020 01:04:29
	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	System	30 Aug 2020 01:04:29
User entered '0'	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:04:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3797c82a-9507-4215-a05c-bcbdec82b0bc'	System	30 Aug 2020 01:04:29
User entered '29 Aug 2020 21:04'	System	30 Aug 2020 01:04:29

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 5'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:24:43', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '79174970-93e8-4b6e-bf31-69c1cae7b28d'	System	31 Aug 2020 02:24:55
User entered 'Yes (Y)'	System	31 Aug 2020 02:24:55

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:24:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '79174970-93e8-4b6e-bf31-69c1cae7b28d'	System	31 Aug 2020 02:24:55
User entered '98.2'	System	31 Aug 2020 02:24:55

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:24:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '79174970-93e8-4b6e-bf31-69c1cae7b28d'	System	31 Aug 2020 02:24:55
User entered 'No (N)'	System	31 Aug 2020 02:24:55

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:24:55', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '79174970-93e8-4b6e-bf31-69c1cae7b28d'	System	31 Aug 2020 02:24:55
User entered '30 Aug 2020 22:24'	System	31 Aug 2020 02:24:55

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 6'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:03:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '10647651-e38a-47c4-900a-902297d4e939'	System	01 Sep 2020 01:03:43
User entered 'Yes (Y)'	System	01 Sep 2020 01:03:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:03:37', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '10647651-e38a-47c4-900a-902297d4e939'	System	01 Sep 2020 01:03:43
User entered '98.4'	System	01 Sep 2020 01:03:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:03:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '10647651-e38a-47c4-900a-902297d4e939'	System	01 Sep 2020 01:03:43
User entered 'No (N)'	System	01 Sep 2020 01:03:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:03:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '10647651-e38a-47c4-900a-902297d4e939'	System	01 Sep 2020 01:03:43
User entered '31 Aug 2020 21:03'	System	01 Sep 2020 01:03:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 7'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:04:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b3524ea4-e988-45ae-bdbb-7b6ec4ce38b6'	System	02 Sep 2020 01:04:43
User entered 'Yes (Y)'	System	02 Sep 2020 01:04:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:04:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b3524ea4-e988-45ae-bdbb-7b6ec4ce38b6'	System	02 Sep 2020 01:04:43
User entered '97.4'	System	02 Sep 2020 01:04:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:04:35', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b3524ea4-e988-45ae-bdbb-7b6ec4ce38b6'	System	02 Sep 2020 01:04:43
User entered 'No (N)'	System	02 Sep 2020 01:04:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:04:37', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b3524ea4-e988-45ae-bdbb-7b6ec4ce38b6'	System	02 Sep 2020 01:04:43
User entered '01 Sep 2020 21:04'	System	02 Sep 2020 01:04:43

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:20', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b778bcc8-e0cd-492b-a4e7-a5f7c58bb8b1'	System	26 Aug 2020 16:02:07
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 16:02:07

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b778bcc8-e0cd-492b-a4e7-a5f7c58bb8b1'	System	26 Aug 2020 16:02:07
User entered 'No (N)'	System	26 Aug 2020 16:02:07

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b778bcc8-e0cd-492b-a4e7-a5f7c58bb8b1'	System	26 Aug 2020 16:02:07
User entered 'No (N)'	System	26 Aug 2020 16:02:07

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b778bcc8-e0cd-492b-a4e7-a5f7c58bb8b1'	System	26 Aug 2020 16:02:07
User entered 'None (1)'	System	26 Aug 2020 16:02:07

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b778bcc8-e0cd-492b-a4e7-a5f7c58bb8b1'	System	26 Aug 2020 16:02:07
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:02:07

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 11:40'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 14:10'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:23', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1f34df65-2f3f-488c-84e1-05980aeb7008'	System	27 Aug 2020 01:34:49
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 01:34:49

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1f34df65-2f3f-488c-84e1-05980aeb7008'	System	27 Aug 2020 01:34:49
User entered 'No (N)'	System	27 Aug 2020 01:34:49

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1f34df65-2f3f-488c-84e1-05980aeb7008'	System	27 Aug 2020 01:34:49
User entered 'No (N)'	System	27 Aug 2020 01:34:49

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1f34df65-2f3f-488c-84e1-05980aeb7008'	System	27 Aug 2020 01:34:49
User entered 'None (1)'	System	27 Aug 2020 01:34:49

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:47', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1f34df65-2f3f-488c-84e1-05980aeb7008'	System	27 Aug 2020 01:34:49
User entered '26 Aug 2020 21:34'	System	27 Aug 2020 01:34:49

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 15:05'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 2'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '435e0525-6e71-4076-a82f-87faf11a4c8b'	System	28 Aug 2020 02:56:35
User entered 'None (1)'	System	28 Aug 2020 02:56:35

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '435e0525-6e71-4076-a82f-87faf11a4c8b'	System	28 Aug 2020 02:56:35
User entered 'No (N)'	System	28 Aug 2020 02:56:35

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '435e0525-6e71-4076-a82f-87faf11a4c8b'	System	28 Aug 2020 02:56:35
User entered 'No (N)'	System	28 Aug 2020 02:56:35

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '435e0525-6e71-4076-a82f-87faf11a4c8b'	System	28 Aug 2020 02:56:35
User entered 'None (1)'	System	28 Aug 2020 02:56:35

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:56:31', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '435e0525-6e71-4076-a82f-87faf11a4c8b'	System	28 Aug 2020 02:56:35
User entered '27 Aug 2020 22:56'	System	28 Aug 2020 02:56:35

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 3'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2572d196-30a2-4019-be63-7e419ee19d03'	System	29 Aug 2020 01:27:23
User entered 'None (1)'	System	29 Aug 2020 01:27:23

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2572d196-30a2-4019-be63-7e419ee19d03'	System	29 Aug 2020 01:27:23
User entered 'No (N)'	System	29 Aug 2020 01:27:23

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:09', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2572d196-30a2-4019-be63-7e419ee19d03'	System	29 Aug 2020 01:27:23
User entered 'No (N)'	System	29 Aug 2020 01:27:23

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2572d196-30a2-4019-be63-7e419ee19d03'	System	29 Aug 2020 01:27:23
User entered 'None (1)'	System	29 Aug 2020 01:27:23

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:20', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2572d196-30a2-4019-be63-7e419ee19d03'	System	29 Aug 2020 01:27:23
User entered '28 Aug 2020 21:27'	System	29 Aug 2020 01:27:23

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 4'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd401aca3-b02a-43a0-bce9-2fd65318ab2d'	System	30 Aug 2020 01:03:41
User entered 'None (1)'	System	30 Aug 2020 01:03:41

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd401aca3-b02a-43a0-bce9-2fd65318ab2d'	System	30 Aug 2020 01:03:41
User entered 'No (N)'	System	30 Aug 2020 01:03:41

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd401aca3-b02a-43a0-bce9-2fd65318ab2d'	System	30 Aug 2020 01:03:41
User entered 'No (N)'	System	30 Aug 2020 01:03:41

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd401aca3-b02a-43a0-bce9-2fd65318ab2d'	System	30 Aug 2020 01:03:41
User entered 'None (1)'	System	30 Aug 2020 01:03:41

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd401aca3-b02a-43a0-bce9-2fd65318ab2d'	System	30 Aug 2020 01:03:41
User entered '29 Aug 2020 21:03'	System	30 Aug 2020 01:03:41

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 5'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:34', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9256e2c9-00f5-4578-aff5-80bae02ea7ec'	System	31 Aug 2020 02:23:48
User entered 'None (1)'	System	31 Aug 2020 02:23:48

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9256e2c9-00f5-4578-aff5-80bae02ea7ec'	System	31 Aug 2020 02:23:48
User entered 'No (N)'	System	31 Aug 2020 02:23:48

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:43', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9256e2c9-00f5-4578-aff5-80bae02ea7ec'	System	31 Aug 2020 02:23:48
User entered 'No (N)'	System	31 Aug 2020 02:23:48

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9256e2c9-00f5-4578-aff5-80bae02ea7ec'	System	31 Aug 2020 02:23:48
User entered 'None (1)'	System	31 Aug 2020 02:23:48

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9256e2c9-00f5-4578-aff5-80bae02ea7ec'	System	31 Aug 2020 02:23:48
User entered '30 Aug 2020 22:23'	System	31 Aug 2020 02:23:48

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 6'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '70d9e8f5-7d74-4fad-84f0-2c5252aa5fc3'	System	01 Sep 2020 01:02:39
User entered 'None (1)'	System	01 Sep 2020 01:02:39

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '70d9e8f5-7d74-4fad-84f0-2c5252aa5fc3'	System	01 Sep 2020 01:02:39
User entered 'No (N)'	System	01 Sep 2020 01:02:39

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '70d9e8f5-7d74-4fad-84f0-2c5252aa5fc3'	System	01 Sep 2020 01:02:39
User entered 'No (N)'	System	01 Sep 2020 01:02:39

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:34', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '70d9e8f5-7d74-4fad-84f0-2c5252aa5fc3'	System	01 Sep 2020 01:02:39
User entered 'None (1)'	System	01 Sep 2020 01:02:39

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '70d9e8f5-7d74-4fad-84f0-2c5252aa5fc3'	System	01 Sep 2020 01:02:39
User entered '31 Aug 2020 21:02'	System	01 Sep 2020 01:02:39

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 7'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c6cddd04-3f53-497a-9df4-8bd0e497a4d6'	System	02 Sep 2020 01:03:56
User entered 'None (1)'	System	02 Sep 2020 01:03:56

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c6cddd04-3f53-497a-9df4-8bd0e497a4d6'	System	02 Sep 2020 01:03:56
User entered 'No (N)'	System	02 Sep 2020 01:03:56

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c6cddd04-3f53-497a-9df4-8bd0e497a4d6'	System	02 Sep 2020 01:03:56
User entered 'No (N)'	System	02 Sep 2020 01:03:56

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c6cddd04-3f53-497a-9df4-8bd0e497a4d6'	System	02 Sep 2020 01:03:56
User entered 'None (1)'	System	02 Sep 2020 01:03:56

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'c6cddd04-3f53-497a-9df4-8bd0e497a4d6'	System	02 Sep 2020 01:03:56
User entered '01 Sep 2020 21:03'	System	02 Sep 2020 01:03:56

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:44', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:47', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:49', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'None (0)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered 'No (N)'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T12:01:55', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f28a103f-02d3-49dd-9628-c184a13a961f'	System	26 Aug 2020 16:02:30
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:02:30

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 11:40'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 14:10'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:34:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'No interference with activity (1)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'None (0)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'None (0)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'None (0)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'None (0)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'None (0)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered 'No (N)'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-26T21:35:13', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9e3aa07d-3be1-4c1a-bb70-323a0ce084be'	System	27 Aug 2020 01:35:17
User entered '26 Aug 2020 21:35'	System	27 Aug 2020 01:35:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '26 Aug 2020 15:05'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 2'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:21', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'None (0)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:35', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:38', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'No interference with activity (1)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'None (0)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'None (0)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered 'No (N)'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-27T22:55:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '7472802e-54a9-4e3b-95f1-bb01dd4aa099'	System	28 Aug 2020 02:55:56
User entered '27 Aug 2020 22:55'	System	28 Aug 2020 02:55:56

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 3'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'None (0)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'None (0)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'None (0)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'None (0)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:43', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'None (0)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:55', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered 'No (N)'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-28T21:27:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f36f190b-c8ac-4bc9-b295-30c78df65f7b'	System	29 Aug 2020 01:28:00
User entered '28 Aug 2020 21:27'	System	29 Aug 2020 01:28:00

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 4'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:02:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'No interference with activity (1)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:02:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'No interference with activity (1)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:01', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'Some interference with activity (2)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'Some interference with activity (2)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'None (0)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'None (0)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:12', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered 'No (N)'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-29T21:03:15', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f71f93ec-9846-454f-bf4d-faa3148dac0c'	System	30 Aug 2020 01:03:17
User entered '29 Aug 2020 21:03'	System	30 Aug 2020 01:03:17

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 5'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:22:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'None (0)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:03', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'Some interference with activity (2)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'None (0)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:12', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'No interference with activity (1)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:15', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'None (0)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:17', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'None (0)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:25', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered 'No (N)'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-30T22:23:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6204b255-a613-43ae-8a61-4e029edf6ebd'	System	31 Aug 2020 02:23:31
User entered '30 Aug 2020 22:23'	System	31 Aug 2020 02:23:31

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 6'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:01:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'None (0)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:01:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'None (0)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:01:55', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'None (0)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'No interference with activity (1)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'None (0)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:08', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'None (0)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:11', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered 'No (N)'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-08-31T21:02:13', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'caba962f-094a-45ca-a3c5-65c6f5cf3581'	System	01 Sep 2020 01:02:14
User entered '31 Aug 2020 21:02'	System	01 Sep 2020 01:02:14

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	26 Aug 2020 15:30:27
User entered 'Day 7'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:20', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'None (0)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:31', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered 'No (N)'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-09-01T21:03:34', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4825cb15-2736-4006-9f14-0a975a9dafa6'	System	02 Sep 2020 01:03:39
User entered '01 Sep 2020 21:03'	System	02 Sep 2020 01:03:39

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:30:27

US3412012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:39:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:30:27

US3412012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:53:04

US3412012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:53:04

US3412012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:53:04

US3412012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:53:04

US3412012

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 15:53:26

US3412012

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	02 Sep 2020 15:53:26

US3412012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 17:56:19

US3412012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '9 Sep 2020'	Mason Urban (b) (4)	09 Sep 2020 17:56:19

US3412012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Sep 2020 17:56:19

US3412012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Mason Urban (b) (4)	09 Sep 2020 17:56:19

US3412012

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 17:56:10

US3412012

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	09 Sep 2020 17:56:10

US3412012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 16:24:54

US3412012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '16 Sep 2020'	Mason Urban (b) (4)	16 Sep 2020 16:24:54

US3412012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	16 Sep 2020 16:24:54

US3412012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Mason Urban (b) (4)	16 Sep 2020 16:24:54

US3412012

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 16:24:59

US3412012

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	16 Sep 2020 16:24:59

US3412012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 15:52:24

US3412012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 15:52:24

US3412012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4)	29 Sep 2020 15:52:24

US3412012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'VISIT3'	System	29 Sep 2020 15:52:24

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)'	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered empty.	System	29 Sep 2020 15:52:45

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01

US3412012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01

US3412012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 15:27:16
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 15:53:00
	Jacob sekinger (b) (4)	
	(b) (4)	

US3412012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 15:27:16
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 15:53:00

US3412012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 15:53:19

US3412012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 15:53:19

US3412012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered '10:58'	Jacob sekinger (b) (4)	29 Sep 2020 15:53:19

US3412012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '23 Sep 2020 10:58'	System	29 Sep 2020 15:53:19

US3412012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:40
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 15:53:36

US3412012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '1'	System	29 Sep 2020 15:53:36

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 64'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-02T10:12:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '77bb6de9-8378-415d-88fc-aeb838736058'	System	02 Oct 2020 14:13:31
User entered 'No (N)'	System	02 Oct 2020 14:13:31

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-02T10:13:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '77bb6de9-8378-415d-88fc-aeb838736058'	System	02 Oct 2020 14:13:31
User entered 'No (N)'	System	02 Oct 2020 14:13:31

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-02T10:13:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '77bb6de9-8378-415d-88fc-aeb838736058'	System	02 Oct 2020 14:13:31
User entered '02 Oct 2020 10:13:27'	System	02 Oct 2020 14:13:31

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 71'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-05T07:40:15', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '59ebc4b7-341d-4508-91e2-77c97eb28ed9'	System	05 Oct 2020 11:40:48
User entered 'No (N)'	System	05 Oct 2020 11:40:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-05T07:40:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '59ebc4b7-341d-4508-91e2-77c97eb28ed9'	System	05 Oct 2020 11:40:48
User entered 'No (N)'	System	05 Oct 2020 11:40:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-05T07:40:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '59ebc4b7-341d-4508-91e2-77c97eb28ed9'	System	05 Oct 2020 11:40:48
User entered '05 Oct 2020 07:40:45'	System	05 Oct 2020 11:40:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 78'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Have you been exposed to someone with 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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Please 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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Please 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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Please 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 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:46:19
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 92'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-29T11:01:48', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b9c09ddd-fca1-4f46-9d5a-6c7e01fb17ce'	System	29 Oct 2020 15:02:48
User entered 'Yes (Y)'	System	29 Oct 2020 15:02:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-29T11:01:54', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b9c09ddd-fca1-4f46-9d5a-6c7e01fb17ce'	System	29 Oct 2020 15:02:48
User entered 'No (N)'	System	29 Oct 2020 15:02:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-29T11:01:57', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b9c09ddd-fca1-4f46-9d5a-6c7e01fb17ce'	System	29 Oct 2020 15:02:48
User entered 'No (N)'	System	29 Oct 2020 15:02:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-29T11:02:04', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b9c09ddd-fca1-4f46-9d5a-6c7e01fb17ce'	System	29 Oct 2020 15:02:48
User entered 'No (N)'	System	29 Oct 2020 15:02:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-10-29T11:02:45', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b9c09ddd-fca1-4f46-9d5a-6c7e01fb17ce'	System	29 Oct 2020 15:02:48
User entered '29 Oct 2020 11:02:45'	System	29 Oct 2020 15:02:48

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 99'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-02T10:43:57', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9f111197-9c11-4e24-b185-bf740b7f1c82'	System	02 Nov 2020 15:44:11
User entered 'No (N)'	System	02 Nov 2020 15:44:11

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-02T10:44:02', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9f111197-9c11-4e24-b185-bf740b7f1c82'	System	02 Nov 2020 15:44:11
User entered 'No (N)'	System	02 Nov 2020 15:44:11

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-02T10:44:09', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9f111197-9c11-4e24-b185-bf740b7f1c82'	System	02 Nov 2020 15:44:11
User entered '02 Nov 2020 10:44:09'	System	02 Nov 2020 15:44:11

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 106'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-11T14:47:39', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'cdcd6732-9338-4f35-8131-499fbc138fa2'	System	11 Nov 2020 19:48:03
User entered 'No (N)'	System	11 Nov 2020 19:48:03

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-11T14:47:50', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'cdcd6732-9338-4f35-8131-499fbc138fa2'	System	11 Nov 2020 19:48:03
User entered 'No (N)'	System	11 Nov 2020 19:48:03

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-11T14:47:59', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'cdcd6732-9338-4f35-8131-499fbc138fa2'	System	11 Nov 2020 19:48:03
User entered '11 Nov 2020 14:47:59'	System	11 Nov 2020 19:48:03

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered 'Day 113'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-18T08:44:26', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2bdc800c-dc6d-4061-9f97-92bb3c368563'	System	18 Nov 2020 13:44:34
User entered 'No (N)'	System	18 Nov 2020 13:44:34

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-18T08:44:28', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2bdc800c-dc6d-4061-9f97-92bb3c368563'	System	18 Nov 2020 13:44:34
User entered 'No (N)'	System	18 Nov 2020 13:44:34

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-18T08:44:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2bdc800c-dc6d-4061-9f97-92bb3c368563'	System	18 Nov 2020 13:44:34
User entered '18 Nov 2020 08:44:33'	System	18 Nov 2020 13:44:34

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 17:47:51

US3412012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:46
Data entry locked.	System	29 Jul 2020 17:47:51
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 17:47:51

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-11-22T12:34:12', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3c8337f6-0022-4083-a852-ed79cc4a93ef'	System	22 Nov 2020 17:34:38
User entered 'No (N)'	System	22 Nov 2020 17:34:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2020-11-22T12:34:24', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3c8337f6-0022-4083-a852-ed79cc4a93ef'	System	22 Nov 2020 17:34:38
User entered 'No (N)'	System	22 Nov 2020 17:34:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-11-22T12:34:33', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '3c8337f6-0022-4083-a852-ed79cc4a93ef' User entered '22 Nov 2020 12:34:33'	System	22 Nov 2020 17:34:38
	System	22 Nov 2020 17:34:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-04T11:44:29', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ced4f18c-6453-4dc4-9e04-a851cf6bf6d4'	System	04 Dec 2020 16:44:44
User entered 'No (N)'	System	04 Dec 2020 16:44:44

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2020-12-04T11:44:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ced4f18c-6453-4dc4-9e04-a851cf6bf6d4'	System	04 Dec 2020 16:44:44
User entered 'No (N)'	System	04 Dec 2020 16:44:44

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-04T11:44:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ced4f18c-6453-4dc4-9e04-a851cf6bf6d4'	System	04 Dec 2020 16:44:44
User entered '04 Dec 2020 11:44:40'	System	04 Dec 2020 16:44:44

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-11T07:30:05', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9b286d4f-9c14-48a2-a1cc-ed9262bbd336'	System	11 Dec 2020 12:30:38
User entered 'No (N)'	System	11 Dec 2020 12:30:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2020-12-11T07:30:30', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9b286d4f-9c14-48a2-a1cc-ed9262bbd336'	System	11 Dec 2020 12:30:38
User entered 'No (N)'	System	11 Dec 2020 12:30:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-11T07:30:36', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '9b286d4f-9c14-48a2-a1cc-ed9262bbd336'	System	11 Dec 2020 12:30:38
User entered '11 Dec 2020 07:30:36'	System	11 Dec 2020 12:30:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-18T06:44:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '28a7af44-cad0-4f92-b755-69327c6b2fdc'	System	18 Dec 2020 11:46:08
User entered 'No (N)'	System	18 Dec 2020 11:46:08

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2020-12-18T06:45:14', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '28a7af44-cad0-4f92-b755-69327c6b2fdc'	System	18 Dec 2020 11:46:08
User entered 'Yes (Y)'	System	18 Dec 2020 11:46:08

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Please 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 (a66dafd0d228b0e2)', Time: '2020-12-18T06:45:40', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '28a7af44-cad0-4f92-b755-69327c6b2fdc'	System	18 Dec 2020 11:46:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 11:46:08

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-18T06:45:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '28a7af44-cad0-4f92-b755-69327c6b2fdc'	System	18 Dec 2020 11:46:08
User entered '18 Dec 2020 06:45:58'	System	18 Dec 2020 11:46:08

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:14', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'Yes (Y)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:11:42', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'Yes (Y)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Please 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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:11:41', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:22', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'Yes (Y)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '0'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '0'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '0'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '0'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '1'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '0'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:52', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered '0'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Please 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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:12:59', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2020-12-27T12:13:10', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9'	System	27 Dec 2020 17:13:43
User entered 'No (N)'	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2020-12-27T12:13:35', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'ee78e925-4f11-4a44-8ef2-5d481bdc14f9' User entered '27 Dec 2020 12:13:35'	System	27 Dec 2020 17:13:43
	System	27 Dec 2020 17:13:43

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-01-03T12:10:07', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd84065a4-b625-4d89-bdfe-c4869a340f26'	System	03 Jan 2021 17:10:37
User entered 'No (N)'	System	03 Jan 2021 17:10:37

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-01-03T12:10:31', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd84065a4-b625-4d89-bdfe-c4869a340f26'	System	03 Jan 2021 17:10:37
User entered 'No (N)'	System	03 Jan 2021 17:10:37

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-01-03T12:10:35', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'd84065a4-b625-4d89-bdfe-c4869a340f26' User entered '03 Jan 2021 12:10:35'	System	03 Jan 2021 17:10:37
	System	03 Jan 2021 17:10:37

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-01-10T00:31:27', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '611c5c11-0e30-418e-9e7f-5e88e6c4b05c'	System	10 Jan 2021 05:31:38
User entered 'No (N)'	System	10 Jan 2021 05:31:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-01-10T00:31:32', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '611c5c11-0e30-418e-9e7f-5e88e6c4b05c'	System	10 Jan 2021 05:31:38
User entered 'No (N)'	System	10 Jan 2021 05:31:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-01-10T00:31:34', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '611c5c11-0e30-418e-9e7f-5e88e6c4b05c' User entered '10 Jan 2021 00:31:34'	System	10 Jan 2021 05:31:38
	System	10 Jan 2021 05:31:38

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-01-17T13:30:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b1d333df-11f3-4bc3-ac63-82872e4a6314'	System	17 Jan 2021 18:31:04
User entered 'No (N)'	System	17 Jan 2021 18:31:04

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-01-17T13:30:58', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b1d333df-11f3-4bc3-ac63-82872e4a6314'	System	17 Jan 2021 18:31:04
User entered 'No (N)'	System	17 Jan 2021 18:31:04

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-01-17T13:31:01', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b1d333df-11f3-4bc3-ac63-82872e4a6314' User entered '17 Jan 2021 13:31:01'	System	17 Jan 2021 18:31:04
	System	17 Jan 2021 18:31:04

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-01-22T06:51:46', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f9e95dbc-c6d0-41af-84f4-27355eb450ff'	System	22 Jan 2021 11:51:58
User entered 'No (N)'	System	22 Jan 2021 11:51:58

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-01-22T06:51:53', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f9e95dbc-c6d0-41af-84f4-27355eb450ff'	System	22 Jan 2021 11:51:58
User entered 'No (N)'	System	22 Jan 2021 11:51:58

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-01-22T06:51:57', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'f9e95dbc-c6d0-41af-84f4-27355eb450ff' User entered '22 Jan 2021 06:51:57'	System	22 Jan 2021 11:51:58
	System	22 Jan 2021 11:51:58

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-02-05T09:03:51', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4259a731-e4c6-4ab2-9c0f-9250f3e431a2'	System	05 Feb 2021 14:04:02
User entered 'No (N)'	System	05 Feb 2021 14:04:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-02-05T09:03:56', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4259a731-e4c6-4ab2-9c0f-9250f3e431a2'	System	05 Feb 2021 14:04:02
User entered 'No (N)'	System	05 Feb 2021 14:04:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-02-05T09:03:59', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '4259a731-e4c6-4ab2-9c0f-9250f3e431a2'	System	05 Feb 2021 14:04:02
User entered '05 Feb 2021 09:03:59'	System	05 Feb 2021 14:04:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-02-19T00:23:06', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6519ca27-8b49-4857-9145-f7f2cf2f8723'	System	19 Feb 2021 05:23:21
User entered 'No (N)'	System	19 Feb 2021 05:23:21

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-02-19T00:23:13', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6519ca27-8b49-4857-9145-f7f2cf2f8723'	System	19 Feb 2021 05:23:21
User entered 'No (N)'	System	19 Feb 2021 05:23:21

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-02-19T00:23:18', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '6519ca27-8b49-4857-9145-f7f2cf2f8723'	System	19 Feb 2021 05:23:21
User entered '19 Feb 2021 00:23:18'	System	19 Feb 2021 05:23:21

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-02-26T08:27:54-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '57488285-c5e1-4dc4-8d18-05ea20831e66'	System	26 Feb 2021 13:29:02
User entered 'No (N)'	System	26 Feb 2021 13:29:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-02-26T08:28:51-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '57488285-c5e1-4dc4-8d18-05ea20831e66'	System	26 Feb 2021 13:29:02
User entered 'No (N)'	System	26 Feb 2021 13:29:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-02-26T08:28:59-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '57488285-c5e1-4dc4-8d18-05ea20831e66'	System	26 Feb 2021 13:29:02
User entered '26 Feb 2021 08:28:59'	System	26 Feb 2021 13:29:02

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-03-05T07:42:21-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a63b8233-2186-47b3-b8e9-59adcb24de3e'	System	05 Mar 2021 12:42:35
User entered 'No (N)'	System	05 Mar 2021 12:42:35

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-03-05T07:42:28-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a63b8233-2186-47b3-b8e9-59adcb24de3e'	System	05 Mar 2021 12:42:35
User entered 'No (N)'	System	05 Mar 2021 12:42:35

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-05T07:42:32-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a63b8233-2186-47b3-b8e9-59adcb24de3e' User entered '05 Mar 2021 07:42:32'	System	05 Mar 2021 12:42:35
	System	05 Mar 2021 12:42:35

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-03-12T16:28:56-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b83f4456-1f86-4b32-8f7a-1c4029bb89ff'	System	12 Mar 2021 21:29:26
User entered 'No (N)'	System	12 Mar 2021 21:29:26

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-03-12T16:29:20-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b83f4456-1f86-4b32-8f7a-1c4029bb89ff'	System	12 Mar 2021 21:29:26
User entered 'No (N)'	System	12 Mar 2021 21:29:26

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-12T16:29:24-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'b83f4456-1f86-4b32-8f7a-1c4029bb89ff' User entered '12 Mar 2021 16:29:24'	System	12 Mar 2021 21:29:26
	System	12 Mar 2021 21:29:26

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-03-19T09:10:52-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0409f003-3105-4022-8618-a5c1f5960939'	System	19 Mar 2021 13:11:07
User entered 'No (N)'	System	19 Mar 2021 13:11:07

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-03-19T09:11:01-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0409f003-3105-4022-8618-a5c1f5960939'	System	19 Mar 2021 13:11:07
User entered 'No (N)'	System	19 Mar 2021 13:11:07

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-19T09:11:05-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '0409f003-3105-4022-8618-a5c1f5960939'	System	19 Mar 2021 13:11:07
User entered '19 Mar 2021 09:11:05'	System	19 Mar 2021 13:11:07

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-03-26T09:13:03-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2e4c4631-9405-4214-a56d-cc47744bc4f1'	System	26 Mar 2021 13:13:17
User entered 'No (N)'	System	26 Mar 2021 13:13:17

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-03-26T09:13:13-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2e4c4631-9405-4214-a56d-cc47744bc4f1'	System	26 Mar 2021 13:13:17
User entered 'No (N)'	System	26 Mar 2021 13:13:17

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-26T09:13:16-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '2e4c4631-9405-4214-a56d-cc47744bc4f1'	System	26 Mar 2021 13:13:17
User entered '26 Mar 2021 09:13:16'	System	26 Mar 2021 13:13:17

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-04-13T06:24:31-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1ad841f2-9f3c-4e68-b821-f1bc5982f0e4' User entered 'No (N)'	System	13 Apr 2021 10:24:40
	System	13 Apr 2021 10:24:40

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-04-13T06:24:33-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1ad841f2-9f3c-4e68-b821-f1bc5982f0e4'	System	13 Apr 2021 10:24:40
User entered 'No (N)'	System	13 Apr 2021 10:24:40

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-04-13T06:24:37-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '1ad841f2-9f3c-4e68-b821-f1bc5982f0e4' User entered '13 Apr 2021 06:24:37'	System	13 Apr 2021 10:24:40
	System	13 Apr 2021 10:24:40

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-04-20T10:03:12-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a70bdbe0-184f-4b83-916b-06d99a643f5e'	System	20 Apr 2021 14:03:22
User entered 'No (N)'	System	20 Apr 2021 14:03:22

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-04-20T10:03:15-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a70bdb0-184f-4b83-916b-06d99a643f5e'	System	20 Apr 2021 14:03:22
User entered 'No (N)'	System	20 Apr 2021 14:03:22

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-04-20T10:03:18-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: 'a70bdbe0-184f-4b83-916b-06d99a643f5e' User entered '20 Apr 2021 10:03:18'	System	20 Apr 2021 14:03:22
	System	20 Apr 2021 14:03:22

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-04-23T23:19:23-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '62406879-0d2d-4835-b676-bfc0f369f79e' User entered 'No (N)'	System	24 Apr 2021 03:20:54
	System	24 Apr 2021 03:20:54

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-04-23T23:19:27-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '62406879-0d2d-4835-b676-bfc0f369f79e' User entered 'No (N)'	System	24 Apr 2021 03:20:54
	System	24 Apr 2021 03:20:54

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-04-23T23:19:31-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '62406879-0d2d-4835-b676-bfc0f369f79e' User entered '23 Apr 2021 23:19:31'	System	24 Apr 2021 03:20:54

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[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 (a66dafd0d228b0e2)', Time: '2021-04-30T07:23:30-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '684541eb-b28b-47b0-bb72-5caa5729e56f' User entered 'No (N)'	System	30 Apr 2021 11:23:46
	System	30 Apr 2021 11:23:46

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Have you been exposed to someone with 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 (a66dafd0d228b0e2)', Time: '2021-04-30T07:23:34-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '684541eb-b28b-47b0-bb72-5caa5729e56f' User entered 'No (N)'	System	30 Apr 2021 11:23:46
	System	30 Apr 2021 11:23:46

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-04-30T07:23:40-04:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '684541eb-b28b-47b0-bb72-5caa5729e56f' User entered '30 Apr 2021 07:23:40'	System	30 Apr 2021 11:23:46
	System	30 Apr 2021 11:23:46

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:46:19

US3412012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:39:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:19
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:46:19

US3412012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:39:31

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 07:15:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-04T11:20:32-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '46bfa114-ed81-4fd7-85d9-2830baf014d0'	System	04 Mar 2021 16:21:19
User entered 'Yes (Y)'	System	04 Mar 2021 16:21:19

US3412012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:39:31

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-04T11:20:40-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '46bfa114-ed81-4fd7-85d9-2830baf014d0'	System	04 Mar 2021 16:21:19
User entered 'No (N)'	System	04 Mar 2021 16:21:19

US3412012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:39:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:15:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a66dafd0d228b0e2)', Time: '2021-03-04T11:21:01-05:00', User OID: 'PatientReportedOutcome (US3412012)', ODM File OID: '46bfa114-ed81-4fd7-85d9-2830baf014d0' User entered '04 Mar 2021 11:21:01'	System	04 Mar 2021 16:21:19
	System	04 Mar 2021 16:21:19

US3412012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Oct 2020 18:11:16

US3412012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered '21 Oct 2020'	Mason Urban (b) (4)	21 Oct 2020 18:11:16

US3412012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Oct 2020 18:11:16

US3412012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered empty.	Mason Urban (b) (4)	21 Oct 2020 18:11:16

US3412012

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Oct 2020 18:11:21

US3412012

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	21 Oct 2020 18:11:21

US3412012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Nov 2020 13:50:16

US3412012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Nov 2020'	Melissa Fuson (b) (4)	30 Nov 2020 13:50:16

US3412012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	30 Nov 2020 13:50:16

US3412012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 13:50:16

US3412012

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	30 Nov 2020 15:06:20

US3412012

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User entered 'I'	System	30 Nov 2020 15:06:20

US3412012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 18:13:01

US3412012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '23 Dec 2020'	Mason Urban (b) (4)	23 Dec 2020 18:13:01

US3412012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Dec 2020 18:13:01

US3412012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Mason Urban (b) (4)	23 Dec 2020 18:13:01

US3412012

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 18:13:21

US3412012

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:41:24
User entered 'I'	System	23 Dec 2020 18:13:21

US3412012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 16:36:04

US3412012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '22 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 16:36:04

US3412012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Jan 2021 16:36:04

US3412012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 16:36:04

US3412012

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 16:36:10

US3412012

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'I'	System	22 Jan 2021 16:36:10

US3412012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:11:08
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample (Accession No: 1F650469999) with date 25-Feb-2021 labelled as Unscheduled; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4)	28 Apr 2021 08:15:41
	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample (Accession No: 1F650469999) with date 25-Feb-2021 labelled as Unscheduled; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' answered with 'This is due to subject presenting for OL-day 1 and decision visit on separate days. originally site was instructed that labs had to be collected on both days. Site collected two sets of labs one for decision visit and one for OL-day 1. However, lab boxes are only provided for OL-day 1. due to site having to use both OL-day 1 kits this cause duplicated visits. Preclarus determined to turn one of them into an unscheduled visit to report all labs.' (Site from DM).	Steven Anderson (b) (4)	26 Mar 2021 15:58:11
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has a Nasopharyngeal Swab Sample (Accession No: 1F650469999) with date 25-Feb-2021 labelled as Unscheduled; however, there is no corresponding record in EDC. Please confirm the correct visit and reconcile. Else clarify. Thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 11:08:27
	(b) (4)	
	(b) (4)	
	Andrea Newlands (b) (4)	25 Feb 2021 19:12:22
	(b) (4)	

US3412012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:11:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	01 Mar 2021 17:59:04
User entered '26 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	01 Mar 2021 17:58:53
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 19:12:22

US3412012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:11:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	25 Feb 2021 19:12:22

US3412012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:11:08
User entered 'VISIT4'	System	25 Feb 2021 19:12:22

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '11:24'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '25 Feb 2021 11:24'	System	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '36.7' C	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '76'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'bpm'	System	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '16'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'breaths/min'	System	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '120'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '80'	Steven Anderson (b) (4)	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered 'mmHg'	System	31 Mar 2021 13:37:54

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01

US3412012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01

US3412012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	25 Feb 2021 19:15:05
User entered 'Yes (Y)'	(b) (4)	
	Andrea Newlands (b) (4)	25 Feb 2021 19:14:29
	(b) (4)	

US3412012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	25 Feb 2021 19:15:05
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 19:14:29

US3412012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26FEB2021 is recorded under Visit 04 Day 209 in EDC, however the same is reported under Unscheduled visit in PPD Central lab with sample collection date of 25FEB2021. Please reconcile the correct Visit and correct Sample date in query response and update if applicable. Else clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 08:06:11
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26FEB2021 is recorded under Visit 04 Day 209 in EDC, however the same is reported under Unscheduled visit in PPD Central lab with sample collection date of 25FEB2021. Please reconcile the correct Visit and correct Sample date in query response and update if applicable. Else clarify, Thank you' answered with 'subject had decision visit on 26jan2021, but ol-d1 on 25feb2021. sample was inadvertently taken during ol-d1. v4 also occurred on 25feb2021. sample taken 25feb2021 should be both v4 and unscheduled. decision/ol-d1 sample date of 26jan2021 is correct.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 20:40:23
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26FEB2021 is recorded under Visit 04 Day 209 in EDC, however the same is reported under Unscheduled visit in PPD Central lab with sample collection date of 25FEB2021. Please reconcile the correct Visit and correct Sample date in query response and update if applicable. Else clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:20:15
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	01 Mar 2021 17:56:24

US3412012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	22 Mar 2021 20:37:27
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	22 Mar 2021 20:37:27
User entered '25 Feb 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 20:37:27
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	01 Mar 2021 17:59:04
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:58:53
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	01 Mar 2021 17:58:53
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Mar 2021 17:56:24
User entered '26 Feb 2021'	Andrea Newlands (b) (4)	01 Mar 2021 17:56:24

US3412012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '11:40'	Andrea Newlands (b) (4)	01 Mar 2021 17:56:24

US3412012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '25 Feb 2021 11:40'	System	22 Mar 2021 20:37:27
User entered '26 Feb 2021 11:40'	System	01 Mar 2021 17:56:24

US3412012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 19:14:36

US3412012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 23:42:01
User entered '1'	System	25 Feb 2021 19:14:36

US3412012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Mar 2021 19:11:30

US3412012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '22 Mar 2021'	Mason Urban (b) (4)	22 Mar 2021 19:11:30

US3412012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Mar 2021 19:11:30

US3412012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Mason Urban (b) (4)	22 Mar 2021 19:11:30

US3412012

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Mar 2021 19:11:33

US3412012

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'I'	System	22 Mar 2021 19:11:33

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Please complete COVID-19 Severity Assessment CRF' (Site from CRA).	(b) (4)	
Query 'Please complete COVID-19 Severity Assessment CRF' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 02:12:02
Query 'Please complete COVID-19 Severity Assessment CRF' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:17:05
User opened query 'Please complete COVID-19 Severity Assessment CRF' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 16:23:57
		28 Jan 2021 15:14:20
User entered '28 Dec 2020'	Melissa Fuson (b) (4)	28 Dec 2020 21:36:22
	(b) (4)	

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:14:20
User entered '13:00'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:36:22

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:19
User entered '28 Dec 2020 13:00'	System	28 Dec 2020 21:36:22

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:14:20
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:36:22

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:39:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:14:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Dec 2020 21:44:34
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:36:22

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered '25 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered missing code ND - Not Done.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered missing code ND - Not Done.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:13
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered '26 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered empty.	System	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered '27 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered empty.	System	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:47:31

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered missing code ND - Not Done.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:47:15
User closed query 'temp = 97.6 per illness visit vitals? Please review and update' (Site from CRA).	(b) (4)	04 Feb 2021 23:47:09
Query 'temp = 97.6 per illness visit vitals? Please review and update' answered with 'UPDATED TO 97.6 F PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4)	28 Jan 2021 16:42:25
User entered '97.6' F reason for change: Data Entry Error	(b) (4)	28 Jan 2021 16:40:48
DataPoint Un-verified.	(b) (4), (b) (6)	28 Jan 2021 15:56:36
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:56:28
User opened query 'temp = 97.6 per illness visit vitals? Please review and update' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:55:12
User entered missing code ND - Not Done.	Melissa Fuson (b) (4)	28 Dec 2020 21:48:50
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:56:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:48:50

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 5 (Day 5)'	Melissa Fuson (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered '29 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered '0'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered '95'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered '99.1' F	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	29 Dec 2020 19:51:29

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered '30 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:26:44
User entered empty.	System	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered '97.5' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Severe (Severe)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Severe (Severe)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:26:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 7 (Day 7)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered '31 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered '94' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:28:54
User entered empty.	System	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered '99.4' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Severe (Severe)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Severe (Severe)' reason for change:	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:24
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:28:54
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 8 (Day 8)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered '1 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered '94' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:30:46
User entered empty.	System	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered '98.3' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:30:46
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 9 (Day 9)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered '2 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered '95' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:32:22
User entered empty.	System	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered '99.3' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:32:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 10 (Day 10)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (10)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered '3 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:34:04
User entered empty.	System	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered '99.4' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:34:04
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 11 (Day 11)'	Melissa Fuson (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered '4 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	04 Jan 2021 20:35:44
User entered empty.	System	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered '98.8' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:07:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Jan 2021 20:35:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 20:23:01

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 12 (Day 12)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '5 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 16:51:23
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.5' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (12)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:51:23
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '6 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '92' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 16:55:32
User entered empty.	System	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '97.3' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:55:32
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 14 (Day 14)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '7 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '95' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 16:57:28
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.7' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:27:51
User closed query 'Per source moderate loss of smell also? Please confirm and update as appropriate' (Site from CRA).		25 Mar 2021 20:27:49
Query 'Per source moderate loss of smell also? Please confirm and update as appropriate' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:18:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 20:18:41
User opened query 'Per source moderate loss of smell also? Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 21:43:34
DataPoint Un-verified.		13 Mar 2021 21:43:04
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:57:28
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 15 (Day 15)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '8 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '98' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 16:59:19
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:28:03
User closed query '99.4 per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:28:01
Query '99.4 per source? Please confirm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:19:20
User entered '99.4' F reason for change: Data Entry Error	(b) (4)	22 Mar 2021 20:19:16
User opened query '99.4 per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 21:44:19
DataPoint Un-verified.		13 Mar 2021 21:43:58
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '98.4' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 16:59:19
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 16 (Day 16)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:19
User closed query 'Is this actually 9 Jan 2021? Please review source and update accordingly' (Site from CRA).		25 Mar 2021 20:28:16
Query 'Is this actually 9 Jan 2021? Please review source and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:17:23
User entered '09 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 20:05:08
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:30
User opened query 'Is this actually 9 Jan 2021? Please review source and update accordingly' (Site from CRA).		13 Mar 2021 21:48:20
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '11 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:09:47
User entered '9 Jan 2021'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:22
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:09:47
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:00:24
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:11:45
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '99.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:28:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:30
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:28:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:30
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	(b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:34
DataPoint Un-verified.		13 Mar 2021 21:52:30
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:11:45
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 17 (Day 17)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
User closed query 'Is this actually 10 Jan 2021? Please review source, reconcile and update accordingly' (Site from CRA).		25 Mar 2021 20:28:44
Query 'Is this actually 10 Jan 2021? Please review source, reconcile and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:17:48
User entered '10 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 20:05:08
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:51:13
User opened query 'Is this actually 10 Jan 2021? Please review source, reconcile and update accordingly' (Site from CRA).		13 Mar 2021 21:51:05
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '11 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:09:47
User entered '10 Jan 2021'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:52:02
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:09:47
User entered '1' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:00:50
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:52:04
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '98' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:14:14
User entered '=98' (non-conformant).	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:14:14
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:52:05
DataPoint Verified.		13 Mar 2021 21:36:44
User entered '99.3' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:52:07
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:52:34
DataPoint Un-verified.		13 Mar 2021 21:52:09
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:28:58
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:37
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:34
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:10
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4)	28 Jan 2021 16:47:48
	Melissa Fuson (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48
	(b) (4)	

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Form: Symptom Log (17)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:28:58
DataPoint Un-verified.		13 Mar 2021 21:52:37
DataPoint Verified.		13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (17)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:28:58
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:52:37
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:13:44
User entered empty.	(b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 18 (Day 18)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '11 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:17:10
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.3' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:17:10
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 19 (Day 19)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '12 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:18:47
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.2' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:18:47
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 20 (Day 20)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '13 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:20:37
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:20:37
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 21 (Day 21)'	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '14 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '94' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:22:22
User entered empty.	System	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '98.6' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:22:22
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:47:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 22 (Day 22)'	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:49:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:49:09
User entered '15 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:49:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:48:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '94' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:24:25
User entered empty.	System	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:24:25
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 23 (Day 23)'	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:49:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:49:09
User entered '16 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:49:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:48:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '95' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:26:17
User entered empty.	System	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '99.6' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:26:17
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 24 (Day 24)'	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:49:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:49:09
User entered '17 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:49:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:48:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:27:50
User entered empty.	System	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '98.9' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:27:50
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 25 (Day 25)'	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:49:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:49:09
User entered '18 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:49:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:48:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '91' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:30:09
User entered empty.	System	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '98.8' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:29:49
User closed query 'None per source? Please confirm and update accordingly' (Site from CRA).	(b) (4)	25 Mar 2021 20:29:47
Query 'None per source? Please confirm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:21:35
User entered 'None (None)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 20:21:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:56:16
User opened query 'None per source? Please confirm and update accordingly' (Site from CRA).	(b) (4)	13 Mar 2021 21:56:12
DataPoint Verified.	(b) (4)	13 Mar 2021 21:36:44
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:30:09
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Day 26 (Day 26)'	Melissa Fuson (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:49:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jan 2021 16:49:09
User entered '19 Jan 2021' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:49:09
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jan 2021 16:48:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User entered '%'	System	28 Jan 2021 17:32:41
User entered empty.	System	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered '98.6' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:39:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:36:44
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:32:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 16:48:47

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[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 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[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 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:49:38
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).		11 Jan 2021 18:18:09
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 'UPDATED AE WITH DIAGNOSIS' (Site from System).	Melissa Fuson (b) (4)	06 Jan 2021 17:27:54
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:25:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:25:48
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	06 Jan 2021 17:25:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 17:25:48
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:49:16
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 21:49:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[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 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:38
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:16

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Folder: Covid-19 Assessment 28 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:39:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:32
User entered 'I'	System	06 Jan 2021 17:25:48

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

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 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:30:29
User closed query 'Subject had O2 = 92 on 06 Jan 2021 and 91 on 18 Jan 2021 - please change to YEs, enter start date 06 Jan 2021, stop date 18 Jan 2021 and O2 = 91' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:30:27
Query 'Subject had O2 = 92 on 06 Jan 2021 and 91 on 18 Jan 2021 - please change to YEs, enter start date 06 Jan 2021, stop date 18 Jan 2021 and O2 = 91' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	22 Mar 2021 20:16:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 20:16:05
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 21:41:55
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:41:49
User opened query 'Subject had O2 = 92 on 06 Jan 2021 and 91 on 18 Jan 2021 - please change to YEs, enter start date 06 Jan 2021, stop date 18 Jan 2021 and O2 = 91' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 21:41:42
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:54:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 18:54:25
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	25 Jan 2021 18:54:25
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 18:54:10
User entered empty.	System	25 Jan 2021 18:54:10
	Melissa Fuson (b) (4)	25 Jan 2021 18:54:10
	(b) (4)	

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:30:31
DataPoint Un-verified.	Andrea Newlands (b) (4)	22 Mar 2021 20:16:31
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Andrea Newlands (b) (4)	22 Mar 2021 20:16:31
	(b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4)	25 Jan 2021 18:54:10
	(b) (4)	

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:30:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	22 Mar 2021 20:16:31
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	22 Mar 2021 20:16:31
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4)	25 Jan 2021 18:54:10

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:30:37
DataPoint Un-verified.	Andrea Newlands (b) (4)	22 Mar 2021 20:16:31
User entered '91' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:16:31
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

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Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[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 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:39:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:41:49
User entered empty.	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:54:10

US3412012

Folder: Covid-19 Assessment 28 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:39:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 21:57:14
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:49:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 21:49:24
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:49:24
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:44:15
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:44:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:44:08
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:37:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:37:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:36:32

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '30 Dec 2020'	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:04:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:34:42
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:31:57
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 17:31:57
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:04:49
User closed query 'Per Lab Recon: Saliva: Per Preclarus report, It appears there is a collection date mismatch between EDC & PPD GCL records for this "COVID PCR Saliva Day 5" sample, as the "date of collection" is recorded as "30 DEC 2020" in EDC, however the same is recorded as "1 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' (Site from DM).		24 Feb 2021 10:14:29
Query 'Per Lab Recon: Saliva: Per Preclarus report, It appears there is a collection date mismatch between EDC & PPD GCL records for this "COVID PCR Saliva Day 5" sample, as the "date of collection" is recorded as "30 DEC 2020" in EDC, however the same is recorded as "1 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' answered with 'confirmed with source 01 jan 2021' (Site from DM).	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:22:25
User entered '01 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:22:07
User opened query 'Per Lab Recon: Saliva: Per Preclarus report, It appears there is a collection date mismatch between EDC & PPD GCL records for this "COVID PCR Saliva Day 5" sample, as the "date of collection" is recorded as "30 DEC 2020" in EDC, however the same is recorded as "1 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:41:12
User entered '30 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 17:34:42
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:04:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 13:33:25
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:31:57
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:04:31
User entered '03 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:22:55
User entered '30 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 13:33:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:02:49
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.'		24 Feb 2021 10:14:35
' (Site from DM). Query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.'	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:24:02
' answered with 'confirmed with source and dates have been updated on edc' (Site from DM). User opened query 'Per GCL Lab Recon: Saliva: Sample dated 05 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.'	(b) (4), (b) (6)	09 Feb 2021 15:30:31
' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 13:33:25
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:31:57
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:02:52
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 01 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM).		24 Feb 2021 10:14:37
Query 'Per GCL Lab Recon: Saliva: Sample dated 01 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' answered with 'confirmed with source and dates for saliva have been updated on edc' (Site from DM).	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:24:27
User entered '05 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:23:30
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 01 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:19:02
User entered '30 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Jan 2021 13:33:25
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:39:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	26 Mar 2021 15:59:48
User closed query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:14:41
Query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' answered with 'confirmed with source saliva collection date and updated on edc' (Site from DM).	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:26:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:25:15
User opened query 'Per GCL Lab Recon: Saliva: Sample dated 03 JAN 2021 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected, then update the details under appropriate visit or provide clarification. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:15:48
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:31:57
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 17:31:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:39:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the same 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) (4), (b) (6)	31 Mar 2021 04:24:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the same 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 'subject did not collect these samples and they were not returned' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Mar 2021 16:00:04
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	26 Mar 2021 15:59:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the same 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)	25 Feb 2021 09:42:33
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness visit in EDC, however the same 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).		25 Feb 2021 09:42:23

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10JAN2021 is recorded under Illness visit in EDC, however the same 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)	25 Feb 2021 09:42:19
User entered '11 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:25:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:39:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Mar 2021 16:08:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:26:54
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 17:31:57
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 17:31:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17
User entered empty.	Melissa Fuson (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:39:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness visit in EDC, however the same 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) (4), (b) (6)	31 Mar 2021 04:24:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness visit in EDC, however the same 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 'site can not determine if these samples were collected or not. it is preumed they were not collected as neither site nor subject have them.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Mar 2021 16:08:39
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	26 Mar 2021 16:08:09
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness visit in EDC, however the same 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)	25 Feb 2021 09:43:13
User entered '17 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:26:54
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:31

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:01:56
User closed query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "26 JAN 2021" is reported under Illness visit "COVID PCR Saliva " in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.		24 Feb 2021 10:14:48
' (Site from DM). Query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "26 JAN 2021" is reported under Illness visit "COVID PCR Saliva " in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:28:07
' answered with 'saliva was collected and edc has been updated' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:27:45
User opened query 'Per Lab Recon: Saliva: Per Preclarus report, Sample dated "26 JAN 2021" is reported under Illness visit "COVID PCR Saliva " in PPD GCL, however the same is missing in EDC under Illness visit in saliva log Day. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	10 Feb 2021 12:46:25
' (Site from DM). User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System). User entered 'No (N)' reason for change: Data Entry Error	System System Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:57 06 Jan 2021 17:31:57 06 Jan 2021 17:31:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 17:31:17

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:01:58
User entered '26 Jan 2021' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 17:27:45
User entered empty.	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:31:17

US3412012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:38:27
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:38:27
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:38:27
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered 'SICKD1'	System	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:47:38
User closed query 'Time of vitals = 1313? 13:00 is time seated - please confirm and update accordingly' (Site from CRA).	(b) (4)	04 Feb 2021 23:47:35
Query 'Time of vitals = 1313? 13:00 is time seated - please confirm and update accordingly' answered with ';UPDATED TO TIME COLLECTED' (Site from CRA).	Melissa Fuson (b) (4)	28 Jan 2021 16:38:38
User entered '13:13' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 16:38:13
User opened query 'Time of vitals = 1313? 13:00 is time seated - please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:48:12
DataPoint Un-verified.	(b) (4)	28 Jan 2021 15:47:08
DataPoint Verified.	(b) (4)	28 Jan 2021 15:47:05
User entered '13:00'	Melissa Fuson (b) (4)	28 Dec 2020 21:34:45

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered '28 Dec 2020 13:13'	System	28 Jan 2021 16:38:13
User entered '28 Dec 2020 13:00'	System	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '168.0' cm	Melissa Fuson (b) (4)	28 Dec 2020 21:34:45
DataPoint set to visible.	(b) (4) System	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '117.7' kg	Melissa Fuson (b) (4)	28 Dec 2020 21:34:45
DataPoint set to visible.	(b) (4) System	28 Dec 2020 21:33:31

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Dec 2020 21:35:02
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	28 Dec 2020 21:35:02
User entered '97.6' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:35:02
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	28 Dec 2020 21:34:45
User entered '97.6' C	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '70'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered 'bpm'	System	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '16'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered 'breaths/min'	System	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '118'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered 'mmHg'	System	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:47:05
User entered '80'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User entered 'mmHg'	System	28 Dec 2020 21:34:45

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21

US3412012

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21

US3412012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:13
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:35:16

US3412012

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:13
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:35:16

US3412012

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:39:31

[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 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:18
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:35:25

US3412012

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:49:18
User entered '28 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:35:25

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:34
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:34
User entered '26 Jan 2021'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:13:34
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered 'SICKD28'	System	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '26 Jan 2021'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '12:36'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered '26 Jan 2021 12:36'	System	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '168.0' cm	Steven Anderson (b) (4)	27 Jan 2021 15:10:07
DataPoint set to visible.	(b) (4) System	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '117.3' kg	Steven Anderson (b) (4)	27 Jan 2021 15:10:07
DataPoint set to visible.	(b) (4) System	27 Jan 2021 15:08:48

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '36.8' C	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered empty.	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '72'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered 'bpm'	System	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '12'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered 'breaths/min'	System	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '126'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered 'mmHg'	System	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:28
User entered '70'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User entered 'mmHg'	System	27 Jan 2021 15:10:07

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:39:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:37
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:16

US3412012

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:37
User entered '26 Jan 2021'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:16

US3412012

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:39:31

[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 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:49
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:25

US3412012

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:39:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:21
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 16:14:49
User entered '26 Jan 2021'	Steven Anderson (b) (4) (b) (4)	27 Jan 2021 15:10:25

US3412012

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:41

US3412012

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '26 Jan 2021'	Steven Anderson (b) (4)	27 Jan 2021 15:10:41

US3412012

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[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 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:41

US3412012

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

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 15:10:41

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '26 Jan 2021'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[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 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:23:52
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 10:45:57

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Andrea Newlands (b) (4)	22 Mar 2021 20:23:52
	(b) (4)	
	System	06 Mar 2021 10:45:57

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '26 Jan 2021'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Placebo (Placebo)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Placebo (Placebo)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Placebo (Placebo)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Mason Urban (b) (4)	04 Mar 2021 16:22:46
User entered 'No (N)'	Steven Anderson (b) (4)	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '1'	System	27 Jan 2021 15:10:59

US3412012

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

Form: Unblinding

Generated On: 11 Aug 2021 22:39:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '1'	System	04 Mar 2021 16:22:46
User entered empty.	System	27 Jan 2021 15:10:59

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '168.5' cm	(b) (4)	
	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55
	(b) (4)	

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '111.8' kg	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '39.37694'	System	22 Mar 2021 20:24:55
DataPoint set to visible.	System	04 Mar 2021 16:22:46

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '168.5' cm	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '111.8' kg	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '39.37694'	System	22 Mar 2021 20:24:55
DataPoint set to visible.	System	04 Mar 2021 16:22:46

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55
	(b) (4)	

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '11:24'	(b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '25 Feb 2021 11:24'	System	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '36.7' C	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (Oral)'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '76'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'bpm'	System	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '16'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'breaths/min'	System	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '120'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'mmHg'	System	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '80'	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'mmHg'	System	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '168.5' cm	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '111.8' kg	Andrea Newlands (b) (4)	22 Mar 2021 20:24:55

US3412012

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:39:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '39.37694'	System	22 Mar 2021 20:24:55
DataPoint set to visible.	System	04 Mar 2021 16:22:46

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '13:21'	(b) (4)	22 Mar 2021 20:25:38
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '25 Feb 2021 13:21'	System	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '97.9' F	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (Oral)'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '72'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'bpm'	System	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '14'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'breaths/min'	System	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '108'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'mmHg'	System	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '62'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:25:38

US3412012

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'mmHg'	System	22 Mar 2021 20:25:38

US3412012

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:47

US3412012

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:47

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Urine (URINE)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Negative (NEGATIVE)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:25:58

US3412012

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

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered empty.	System	22 Mar 2021 20:25:58

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

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 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'mRNA-1273'	System	22 Mar 2021 20:26:19
DataPoint set to visible.	System	04 Mar 2021 16:22:46

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	(b) (4) Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '12:50'	Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '25 Feb 2021 12:50'	System	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Right Arm (RIGHT ARM)'	Andrea Newlands (b) (4)	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'ONCE'	System	22 Mar 2021 20:26:19

US3412012

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

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 20:26:19

US3412012

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	27 Jan 2021 15:11:20

US3412012

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '26 Jan 2021'	Steven Anderson (b) (4)	27 Jan 2021 15:11:20

US3412012

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '12:45'	Steven Anderson (b) (4)	27 Jan 2021 15:11:20

US3412012

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '26 Jan 2021 12:45'	System	27 Jan 2021 15:11:20

US3412012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	27 Jan 2021 15:11:30

US3412012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '26 Jan 2021'	Steven Anderson (b) (4)	27 Jan 2021 15:11:30

US3412012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '12:47'	Steven Anderson (b) (4)	27 Jan 2021 15:11:30

US3412012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:39:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '26 Jan 2021 12:47'	System	27 Jan 2021 15:11:30

US3412012

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

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 16:23:05

US3412012

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

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'I'	System	04 Mar 2021 16:23:05

US3412012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User closed query 'Please complete OL-D29 visit CRFs from 25 Feb 2021' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 12:06:35
Query 'Please complete OL-D29 visit CRFs from 25 Feb 2021' answered with '25feb2021 is ol-d1, ol-d1 crf updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 20:23:47
User opened query 'Please complete OL-D29 visit CRFs from 25 Feb 2021' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 13:08:44
User signature succeeded.	Richard Powell (b) (4) (b) (4)	10 Mar 2021 19:25:49
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	04 Mar 2021 16:23:42

US3412012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered '4 Mar 2021'	Mason Urban (b) (4)	04 Mar 2021 16:23:42

US3412012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Mar 2021 16:23:42

US3412012

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered empty.	Mason Urban (b) (4)	04 Mar 2021 16:23:42

US3412012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:49
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 16:23:50

US3412012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User entered 'I'	System	04 Mar 2021 16:23:50

US3412012

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:19
User entered '1'	System	04 Mar 2021 16:23:50
DataPoint set to visible.	System	04 Mar 2021 16:23:50

US3412012

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:26:59

US3412012

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:26:59

US3412012

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:26:59

US3412012

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:39:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	29 Mar 2021 19:26:59

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:39:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:10

US3412012

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3412012

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:39:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Test performed](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Result](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection time](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:19

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		29 Mar 2021 19:27:35
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 19:27:35
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	29 Mar 2021 19:27:24
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:24
DataPoint set to visible.	System	04 Mar 2021 16:23:50

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:39:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:24

US3412012

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:41

US3412012

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:27:41

US3412012

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 18:32:42
User entered 'Yes (Y)' reason for change: New Information		07 Apr 2021 18:32:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:27:48

US3412012

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:32:42
User entered '7 Apr 2021' reason for change: New Information		07 Apr 2021 18:32:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:27:48

US3412012

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 18:32:42
User entered 'Contact Made (CONTACT MADE)'		07 Apr 2021 18:32:42
reason for change: New Information		
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 19:27:48

US3412012

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:39:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:48

US3412012

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:51

US3412012

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:39:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:27:51

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:31

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:15
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 25FEB2021 is recorded under Unscheduled in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		25 Apr 2021 17:45:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 25FEB2021 is recorded under Unscheduled in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' answered with 'site does not see where this is recorded in COVID-19 assessment. this is the correct date of the immunogenicity assessment. Site was instructed that if ol day 1 and decision day visit were separated labs should be collected on both days. However, this was incorrect so lab separated to unscheduled and OL D1' (Site from DM).	(b) (4) Steven Anderson (b) (4)	09 Apr 2021 16:36:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 25FEB2021 is recorded under Unscheduled in PPD Central lab, however the same collection date is recorded in Covid-19 Assessments corresponding visit details not updated in EDC. Please reconcile the data and amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 04:24:29
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	22 Mar 2021 20:31:45

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:31

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
User entered '0'	Andrea Newlands (b) (4)	22 Mar 2021 20:31:45

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:31

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
User entered '0'	Andrea Newlands (b) (4)	22 Mar 2021 20:31:45

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:31

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
User entered 'I'	Andrea Newlands (b) (4)	22 Mar 2021 20:31:45

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:39:31

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:15
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:51:55
User entered '0'	Andrea Newlands (b) (4)	22 Mar 2021 20:31:45

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Mar 2021 20:32:00

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	22 Mar 2021 20:32:00

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '11:52'	Andrea Newlands (b) (4)	22 Mar 2021 20:32:00

US3412012

Folder: Unscheduled 25 Feb 2021

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:39:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:45:20
User entered '25 Feb 2021 11:52'	System	22 Mar 2021 20:32:00

US3412012

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:39:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:11:43
DataPoint Verified.		13 Apr 2021 14:34:44
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:20
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:58:37

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Breast signs and symptoms, PT: Breast pain, LLT: Soreness breast - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Sep 2020 15:28:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:28:44
Data point term sent to Coder	System	14 Sep 2020 15:00:46
User entered 'BILATERAL BREAST SORENESS'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	16 Sep 2020 23:38:04
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	14 Sep 2020 14:59:54
User entered '01 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User entered empty.	System	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '05 Aug 2020'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54
	(b) (4)	

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User entered empty.	System	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	14 Sep 2020 15:00:42
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		14 Sep 2020 15:00:42
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	14 Sep 2020 14:59:54
User entered '0'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty; reason for change Data Entry Error	(b) (4) Mylene Asmar-Rios	14 Sep 2020 15:00:42
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54
	(b) (4)	

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'None (NONE)'	(b) (4) Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'I'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 14:59:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[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 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Mylene Asmar-Rios	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User entered '0'	System	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User entered '0'	System	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:39:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:38:50
User entered '0'	System	14 Sep 2020 14:59:54

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:09:22
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:29
User entered		
'USA-US061-2021-mRNA-1273-P301000002'	System	07 Jan 2021 14:28:24
User entered 'New'	(b) (4), (b) (6)	07 Jan 2021 14:28:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:09:24
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)	27 Jan 2021 15:14:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 15:14:03
Data point term sent to Coder	System	27 Jan 2021 15:13:47
Coding entries removed.	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
	(b) (4)	
User entered 'Symptomatic COVID - 19' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
	(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.	Coder Import (b) (4)	06 Jan 2021 17:27:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 17:27:42
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 17:27:21
Coding entries removed.	Melissa Fuson (b) (4)	06 Jan 2021 17:26:55
	(b) (4)	
User entered 'COVID - 19' reason for change: Data Entry Error	Melissa Fuson (b) (4)	06 Jan 2021 17:26:55
	(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.	Coder Import (b) (4)	05 Jan 2021 00:46:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Jan 2021 00:46:35
	(b) (4)	
Data point term sent to Coder	System	04 Jan 2021 23:27:54
Coding entries removed.	Steven Anderson (b) (4)	04 Jan 2021 23:27:28
	(b) (4)	
User entered 'CODID - 19' reason for change: Data Entry Error	Steven Anderson (b) (4)	04 Jan 2021 23:27:28
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 21:32:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Dec 2020 21:32:23
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	28 Dec 2020 21:32:09
User entered 'URI'	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	06 Jan 2021 17:26:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '25 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:10:28
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).		02 Feb 2021 13:49:28
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 'this has been updated with the end date of when the symptoms stopped' (Site from Safety).	Steven Anderson (b) (4)	27 Jan 2021 15:14:09
	(b) (4)	
User entered '19 Jan 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
	(b) (4)	
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 21:41:23
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:10:28
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		02 Feb 2021 13:49:37
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.'	Steven Anderson (b) (4)	27 Jan 2021 15:14:43
answered with 'this has been updated to portray as not related per query.' (Site from Safety).	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.'	(b) (4), (b) (6)	14 Jan 2021 21:42:33
(Site from Safety).		
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:31:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 21:31:30
User entered 'Not Applicable (NOT APPLICABLE)'	Melissa Fuson (b) (4)	28 Dec 2020 21:31:30
reason for change: Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 21:31:19
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19
	(b) (4)	

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Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'Not Applicable (NOT APPLICABLE)'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered '0'	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 22:10:28
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).		02 Feb 2021 13:49:32
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 'this has been updated as recovered/resolved due to symptoms ending' (Site from Safety).	Steven Anderson (b) (4)	27 Jan 2021 15:15:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4)	27 Jan 2021 15:13:46
Data Entry Error	(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)	14 Jan 2021 21:41:37
User entered 'Unknown (UNKNOWN)'	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19
	(b) (4)	

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Generated On: 11 Aug 2021 22:39:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 22:10:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	28 Dec 2020 21:31:19

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:08
User closed query 'please provide complete chronological narrative through resolution of AE' (Site from CRA).		25 Mar 2021 20:25:06
User closed query 'PV Query: Days 16, 17, and 18 on symptom log were reported with the same date of 11 Jan 2021. Please review dates and update accordingly. Otherwise, please clarify.' (Site from Safety).		25 Mar 2021 19:48:16
User entered 'SUBJECT'S DAUGHTER HAD COVID-19. SUBJECT STARTED EXPERIENCING SYMPTOMS OF COUGH, FEVER, CHILLS ON 25DEC2020. SHE NO LONGER HAS A FEVER BUT COMPLAINS OF MILD COUGH, LOSS OF SMELL, AND FAITGUE. ON 29DEC2020 SUBJECT REPORTED FEELING WORSE. ON 03JAN2021 SUBJECT STATED THEY HAD ONE TIME DIARRHEA BUT WAS FEELING GREAT. ON 04JAN SUBJECT IS FEELING BETTER AND ONLY HAS EXPERIENCED MILD SHORTNESS OF BREATH AND MILD FATIGUE, ONLY MILD FATIGUE ON 05JAN2021. subject experienced mild-moderate symptoms until ALL SYMPTOMS RESOLVED 19JAN2021.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 20:14:32
Query 'please provide complete chronological narrative through resolution of AE' answered with 'updated' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	22 Mar 2021 20:13:15
	(b) (4)	

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Generated On: 11 Aug 2021 22:39:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject's daughter had covid-19. subject started experiencing symptoms of cough, fever, chills on 25dec2020. she no longer has a fever but complains of mild cough, loss of smell, and fatigue. on 29dec2020 subject reported feeling worse. on 03jan2021 subject stated they had one time diarrhea but was feeling great. on 04jan subject is feeling better and only has experienced mild shortness of breath and mild fatigue, only mild fatigue on 05Jan2021. all symptoms resolved 19jan2021.' reason for change: Data Entry Error Query 'PV Query: Days 16, 17, and 18 on symptom log were reported with the same date of 11 Jan 2021. Please review dates and update accordingly. Otherwise, please clarify.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	22 Mar 2021 20:13:15
User opened query 'please provide complete chronological narrative through resolution of AE' (Site from CRA). DataPoint Verified.	(b) (4)	(b) (4)
User opened query 'PV Query: Days 16, 17, and 18 on symptom log were reported with the same date of 11 Jan 2021. Please review dates and update accordingly. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	13 Mar 2021 22:11:56
User closed query 'PV Query: Please clarify when the subject experienced fever and when fever stopped.' (Site from Safety).	(b) (4), (b) (6)	13 Mar 2021 22:10:28
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 13:00:12
Query 'PV Query: Please clarify when the subject experienced fever and when fever stopped.' answered with 'date has been updated with fever onset of 25-Dec-2020 and resolved by 28-Dec-2020' (Site from Safety).	Steven Anderson (b) (4)	02 Feb 2021 13:49:35
	(b) (4)	02 Feb 2021 13:49:33

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT COMPLAINED OF COUGH, FEVER AND CHILLS ONSET 25-DEC-2020. SHE NO LONGER HAS A FEVER ended by office visit of 28-Dec-2020. SHE COMPLAINED MILD SYMPTOMS OF COUGH AND FATIGUE.' reason for change: Data Entry Error	Steven Anderson (b) (4)	27 Jan 2021 15:20:15
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 'subject did not take any medications for this ae. there was also no surgery or procedures performed either.' (Site from Safety).	Steven Anderson (b) (4)	27 Jan 2021 15:19:11
User opened query 'PV Query: Please clarify when the subject experienced fever and when fever stopped.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 21:42:56
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)	14 Jan 2021 21:41:49
User entered 'SUBJECT COMPLAINED OF COUGH, FEVER AND CHILLS ONSET 25-DEC-2020. SHE NO LONGER HAS A FEVER. SHE COMPLAINED MILD SYMPTOMS OF COUGH AND FATIGUE.' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Dec 2020 21:33:13
User entered empty.	Melissa Fuson (b) (4)	28 Dec 2020 21:31:19

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 21:31:19

US3412012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 21:31:19

US3412012

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:49:47
User entered empty.		29 Jan 2021 14:28:37

US3412012

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	28 Jan 2021 17:44:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jan 2021 17:44:23
Data point term sent to Coder	System	28 Jan 2021 17:43:54
User entered 'PRE DIABETES'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'PV Query Urgent: Since an event of Covid-19 has been reported, and not the diagnosis itself, please update answer to 'No'. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 02:56:08
Query 'PV Query Urgent: Since an event of Covid-19 has been reported, and not the diagnosis itself, please update answer to 'No'. ' answered with 'answer has been updated to no since its not a covid-19 event ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:03:36
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Feb 2021 16:03:13
User opened query 'PV Query Urgent: Since an event of Covid-19 has been reported, and not the diagnosis itself, please update answer to 'No'. ' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:28:33
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '30 Nov 2020'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Melissa Fuson (b) (4)	28 Jan 2021 17:42:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'I'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

US3412012

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Jan 2021 17:42:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Jan 2021 17:42:49

US3412012

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:39:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 17:42:49

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:39:31

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:11:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:30:29
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:05:46
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'information has been updated' (Site from DM).		08 Apr 2021 18:39:52
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).		23 Mar 2021 09:02:06
User closed query 'Per CDM: Diary Dose 2, Log Lines 3 and 5, ediary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).		13 Oct 2020 08:58:01

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:39:31

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM: Diary Dose 2, Log Lines 3 and 5, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' answered with 'subject stated recording error ' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 18:46:17
User opened query 'Per CDM: Diary Dose 2, Log Lines 3 and 5, diary reports medication was taken for pain or fever, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:05:50
User entered 'Yes (Y)' reason for change: New Information	Zachary Eardley (b) (4)	05 Aug 2020 22:44:19
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 15:08:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 16:37:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	11 Aug 2020 16:37:13
Data point term sent to Coder	System	11 Aug 2020 14:02:37
Coding entries removed.	Zachary Eardley (b) (4)	11 Aug 2020 14:01:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 22:47:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Aug 2020 22:47:06
Data point term sent to Coder	System	05 Aug 2020 22:46:08
User entered 'Advil'	Zachary Eardley (b) (4)	05 Aug 2020 22:45:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4)	05 Aug 2020 22:45:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIAS, ARTHALGIAS GENERALIZED is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIAS, ARTHALGIAS GENERALIZED did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:10:50
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIAS, ARTHALGIAS GENERALIZED is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIAS, ARTHALGIAS GENERALIZED did not meet the AE reporting criteria. ' answered with 'did not meet adverse event reporting criteria. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 15:57:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIAS, ARTHALGIAS GENERALIZED is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIAS, ARTHALGIAS GENERALIZED did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:20:23
User entered 'myalgias, arthalgias generalized (solicited)' reason for change: Data Entry Error	Zachary Eardley (b) (4)	11 Aug 2020 14:01:59
User entered 'muscle aches'	Zachary Eardley (b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '200'	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'mg (mg)'	(b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'other (OTHER)'	(b) (4) Zachary Eardley (b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '4 tablets for one day.'	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (ORAL)'	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '01 Aug 2020'	(b) (4)	05 Aug 2020 22:45:25
	Zachary Eardley (b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	(b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '01 Aug 2020'	(b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	(b) (4)	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User entered empty.	System	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User entered empty.	System	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:20
User entered empty.	System	05 Aug 2020 22:45:25

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: BUPRENORPHINE HYDROCHLORIDE;NALOXONE HYDROCHLORIDE, PRODUCTSYNONYM: SUBOXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 01:16:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 01:16:16
Data point term sent to Coder	System	19 Aug 2020 18:42:29
User entered 'SUBONXONE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'OPIOID ABUSE REMISSION'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '8'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:14:19
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	19 Aug 2020 18:42:17
User entered 'UN UNK 2007'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:42:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:42:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 22:50:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:50:10
Data point term sent to Coder	System	19 Aug 2020 18:43:31
User entered 'BUMETANIDE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'LOWER EXTREMITY EDEMA'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '1'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:11:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:01:15
User entered 'UN UNK 2018' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:01:06
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2017). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:20:45
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 01:14:19
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	19 Aug 2020 18:43:24
User entered 'UN UNK 2016'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:43:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:43:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 18:46:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:46:27
Data point term sent to Coder	System	19 Aug 2020 18:45:35
User entered 'ONDANSETRON'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:45:03

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'NAUSEA'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '4'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'as needed (PRN)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:14:19
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	19 Aug 2020 18:45:03
User entered '01 Feb 2020'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:45:03

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:45:03
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:45:03

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:45:03

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 18:45:03

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Aug 2020 11:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:03:31
Data point term sent to Coder	System	19 Aug 2020 18:47:40
User entered 'XFACTOR PLUS MULTIVITAMIN'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'GENERAL HEALTH'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '2'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'capsule (CAPSULE)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:14:19
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	19 Aug 2020 18:47:24
User entered '01 Jan 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:47:24
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:47:24

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Sep 2020 12:06:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 12:06:55
Data point term sent to Coder	System	19 Aug 2020 18:48:42
User entered 'VITAL BIOME'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:48:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '1-2'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'capsule (CAPSULE)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:14:19
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	19 Aug 2020 18:48:17
User entered '01 Jan 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 18:48:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 18:48:17
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:48:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:48:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 18:48:17

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 15:04:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:04:50
Data point term sent to Coder	System	14 Sep 2020 15:03:55
User entered 'BIOTIN'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:02:24
Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:59:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:59:23
User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 04:49:47
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '1000'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available equivalent option instead of Other for Dose Unit. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 04:21:28
Query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available equivalent option instead of Other for Dose Unit. Please review and update as appropriate.' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:01:57
User entered 'ug (ug)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:01:48
User opened query 'Per CDM: Dose unit is recorded as 'Other' and If dose unit is Other, specify is recorded as 'MCG'. However 'ug' is an available equivalent option instead of Other for Dose Unit. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:22:40
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	29 Sep 2020 16:01:48
	(b) (4)	
User entered 'MCG'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '01 Apr 2020'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	14 Sep 2020 15:03:13
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 15:03:13

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:44:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:44:26
Data point term sent to Coder	System	05 Oct 2020 15:58:43
User entered 'ibuprofen'	Jacob sekinger (b) (4) (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'solicited myalgia, arthralgias'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '200'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'mg (mg)'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'once daily (QD)'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '1 Aug 2020'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '0'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Jacob sekinger (b) (4)	05 Oct 2020 15:58:24
User entered 'Yes (Y)'	(b) (4)	
	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	05 Oct 2020 15:58:24
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	05 Oct 2020 15:58:14
User entered '1 Aug 2020'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User entered '1'	System	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User entered '1'	System	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:14:28
User entered '804 (804)'	System	05 Oct 2020 15:58:14

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
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.	(b) (4) Coder Import (b) (4)	01 Dec 2020 09:28:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 09:28:08
Data point term sent to Coder	System	30 Nov 2020 14:05:35
User entered 'METFORMIN'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'OBESITY / WEIGHT LOSS / BORDER LINE DIABETIC'	(b) (4) Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered '500'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered 'twice daily (BID)'	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '20 Nov 2020'	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	30 Nov 2020 14:04:40
	(b) (4)	

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered empty.	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Nov 2020 14:04:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 18:41:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 18:41:48
Data point term sent to Coder User entered 'Botox'	System (b) (4), (b) (6)	08 Apr 2021 18:40:32 08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'cosmetic'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'injection'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User entered empty.	System	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User entered empty.	System	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:39:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:57
User entered empty.	System	08 Apr 2021 18:39:40

US3412012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:39:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 15:08:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'USA-US061-2021-MRNA-1273-P301000002'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Richard'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gregory'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Powell'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gottschlich'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '4260 Glendale Milford Road'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Cincinnati'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'OH'	System	25 Mar 2021 19:48:46

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '45242'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		02 Feb 2021 13:49:55
User entered 'US'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 19:48:46
User entered '2'	System	02 Feb 2021 13:50:03
User entered '1'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'USA-US061-2021-MRNA-1273-P301000002'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Richard'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gregory'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Powell'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gottschlich'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '4260 Glendale Milford Road'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Cincinnati'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'OH'	System	25 Mar 2021 19:48:46

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '45242'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		02 Feb 2021 13:49:55
User entered 'US'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 19:48:46
User entered '2'	System	02 Feb 2021 13:50:03
User entered '1'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered '07/Jan/2021 14:28'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:39:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		02 Feb 2021 13:49:55
User entered 'I'		07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'USA-US061-2021-MRNA-1273-P301000002'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	25 Mar 2021 20:25:25
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Richard'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gregory'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Powell'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gottschlich'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '4260 Glendale Milford Road'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Cincinnati'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'OH'	System	25 Mar 2021 19:48:46

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '45242'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		02 Feb 2021 13:49:55
User entered 'US'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 19:48:46
User entered '2'	System	02 Feb 2021 13:50:03
User entered '1'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered '02/Feb/2021 08:50'	System	02 Feb 2021 13:50:03

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:39:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'I'		02 Feb 2021 13:50:03

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'USA-US061-2021-MRNA-1273-P301000002'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		07 Jan 2021 14:28:47
User entered 'No (N)'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Richard'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gregory'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered 'Powell'	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Gottschlich'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '4260 Glendale Milford Road'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered 'Cincinnati'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'OH'	System	25 Mar 2021 19:48:46

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 20:25:25
Un-reviewed for Safety.	System	25 Mar 2021 19:48:46
User entered empty.	System	25 Mar 2021 19:48:46
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 14:28:47
User entered '45242'	System	07 Jan 2021 14:28:24

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
Reviewed for Safety.		02 Feb 2021 13:49:55
User entered 'US'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:39:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 19:48:46
User entered '2'	System	02 Feb 2021 13:50:03
User entered '1'	System	07 Jan 2021 14:28:55

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:39:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered '25/Mar/2021 15:48'	System	25 Mar 2021 19:48:46

US3412012

Folder: SAE USA-US061-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:39:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:25:25
User entered 'I'		25 Mar 2021 19:48:46