

US3112219 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:50:29

All time stamps listed in this document are displayed in GMT

US3112219

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Participant ID

US3112219

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

US3112219

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
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	False
Black	True
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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" 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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	THYROMEGALY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	NUTRITIONAL DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	NEAR SIGHTED
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	J TUBE
Start date (dd MMM yyyy)	01 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	09 OCT 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	OCT 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	BARIATRIC SURGERY
Start date (dd MMM yyyy)	31 DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	BREAST REDUCTION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Condition	TURBINATE REDUCTION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:32 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:32
Height (<i>xxx.x</i>)	61 in
Weight (<i>xxx.x</i>)	144 lb
BMI (<i>xxx.x</i>)	27.26545 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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Date of assessment (dd MMM yyyy) 12 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	12 AUG 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) 19 Feb 2021 17:01:04

Generated On: 11 Aug 2021 21:50:29

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 17:01:04

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
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) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103692

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	15:32 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:32
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	17:29 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:29
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	074 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

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) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 AUG 2020

What was the treatment time? (00:00-23:59) 16:58 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 16:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

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

Collection date (dd MMM yyyy)	12 AUG 2020
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Collection time (00:00-23:59)	16:08 (24 HR)
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Collection date and time (derived)	12 AUG 2020 16:08
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:48	12 AUG 2020 15:48
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

12 AUG 2020 17:32

PC Open Date & Time

12 AUG 2020 17:18

PC Close Date & Time

12 AUG 2020 19:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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	12 AUG 2020 20:53
PC Open Date & Time	12 AUG 2020 20:43
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °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

13 AUG 2020 21:25

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 14 AUG 2020 14:03

PC Open Date & Time 14 AUG 2020 12:00

PC Close Date & Time 15 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °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

15 AUG 2020 20:12

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

16 AUG 2020 12:00

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

17 AUG 2020 14:47

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 06:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 17:34

PC Open Date & Time

12 AUG 2020 17:18

PC Close Date & Time

12 AUG 2020 19:48

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 20:53

PC Open Date & Time

12 AUG 2020 20:43

PC Close Date & Time

13 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 21:26

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 20:12

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:01

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 14:47

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 06:00

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 17:34
PC Open Date & Time	12 AUG 2020 17:18
PC Close Date & Time	12 AUG 2020 19:48

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 20:54
PC Open Date & Time	12 AUG 2020 20:43
PC Close Date & Time	13 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:26
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:04
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 20:13
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2790

EAB) (1725)

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2790

EAB) (1725)

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 14:55
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:44:52

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:44:52

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:44:17

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:44:17

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:44:17

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:44:17

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 08:20
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 09:44
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	9 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 9 SEP 2020

What was the treatment time? (00:00-23:59) 9:13 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 9:13

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

What was the frequency of the study treatment dosing? ONCE

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

US3112219

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

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

Collection date (dd MMM yyyy)	9 SEP 2020
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Collection time (00:00-23:59)	08:40 (24 HR)
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Collection date and time (derived)	9 SEP 2020 08:40
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US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:27	9 SEP 2020 08:27
Nasopharyngeal Swab 2	No		

US3112219

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:44

PC Open Date & Time

09 SEP 2020 09:33

PC Close Date & Time

09 SEP 2020 12:03

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	09 SEP 2020 12:58
PC Open Date & Time	09 SEP 2020 12:58
PC Close Date & Time	10 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 SEP 2020 18:26

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 12 SEP 2020 12:00

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 14 SEP 2020 09:38

PC Open Date & Time 13 SEP 2020 12:00

PC Close Date & Time 14 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.6 °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

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.5 °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

15 SEP 2020 15:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 09:44

PC Open Date & Time

09 SEP 2020 09:33

PC Close Date & Time

09 SEP 2020 12:03

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:58

PC Open Date & Time

09 SEP 2020 12:58

PC Close Date & Time

10 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:26

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 09:38

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:00

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 15:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 09:44
PC Open Date & Time	09 SEP 2020 09:33
PC Close Date & Time	09 SEP 2020 12:03

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 12:58
PC Open Date & Time	09 SEP 2020 12:58
PC Close Date & Time	10 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:27
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 09:38
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:00
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 15:27
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112219

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:44:52

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:44:52

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	7:52 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 7:52
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112219

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3112219

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	9 OCT 2020
Collection time (<i>00:00-23:59</i>)	7:56 (24 HR)
Collection date and time (derived)	9 OCT 2020 7:56

US3112219

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:06:22

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 11:03:09
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 11:01:08

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 07:29:14

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 08:19:03

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 15:11:24
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 09:30:38

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 10:26:50
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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



Date and time of submission	21 DEC 2020 08:57:54
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 DEC 2020 12:00:24
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 JAN 2021 13:46:23
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 15:15:33
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 20:06:56
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 08:01:31
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 FEB 2021 22:35:00
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 17:59:28
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	05 MAR 2021 20:35:06
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 16:05:20
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 09:07:12

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 12:34:22
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:00:21

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 06:53:25

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 17:59:29

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 22:04:19

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAY 2021 12:00:23
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 397

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 530

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 572

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

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15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 642

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 719

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

DAY 796

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

Have you been exposed to someone with known SARS-CoV-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 ☐

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3112219

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:50:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 17:59:21

US3112219

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:51:02

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:51:02

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

CALL NOT MADE DUE TO
SUBJECT BEING IN ILLNESS
PHASE

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:16:26

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	19 MAR 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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US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 08:55
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112219

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3112219

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

09:40 (24 HR)

Collection date and time (derived)

19 MAR 2021 09:40

US3112219

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 00:08:18

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 00:08:18

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Date of Contact	16 DEC 2020
Time of Contact	10:33
Date and Time of Contact (derived)	16 DEC 2020 10:33
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 16 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	18 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	99.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	19 DEC 2020
------	-------------

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

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

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

Temperature	98.7 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	20 DEC 2020
------	-------------

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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 16 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	21 DEC 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	99.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 16 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	22 DEC 2020
------	-------------

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

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

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

Temperature	99.6 F
-------------	--------

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 (7)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 16 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 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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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 (11)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 (12)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Date	30 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	99 F
-------------	------

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

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

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 (14)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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 16 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 16 Dec 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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 16 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 16 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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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Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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

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

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

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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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 16 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input 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 16 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input 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 16 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 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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EAB) (1725)

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Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Date of Visit	16 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	16 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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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 17 DEC 2020

End Date 17 DEC 2020

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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 DEC 2020
Day 5	Yes	20 DEC 2020
Day 7	Yes	22 DEC 2020
Day 9	Yes	24 DEC 2020
Day 14	Yes	29 DEC 2020
Day 21	Yes	5 JAN 2021
Day 28	Yes	13 JAN 2021

US3112219

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	16 DEC 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	SICKD1
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US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:40 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 11:40
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112219

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 DEC 2020

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

US3112219

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 DEC 2020

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	17:58 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 17:58
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3112219

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3112219

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	15 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3112219

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Date of updated informed consent (<i>dd MMM yyyy</i>)	6 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	15 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3112219

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3112219

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 14:16
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 FEB 2021
Time of assessment (00:00-23:59)	15:22 (24 HR)
Vital Signs Date and Time (derived)	15 FEB 2021 15:22
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 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

US3112219

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 FEB 2021

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

US3112219

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

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	15 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3112219

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 14:51 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 14:51

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

US3112219

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

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

Collection date (dd MMM yyyy)	15 FEB 2021
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Collection time (00:00-23:59)	14:35 (24 HR)
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Collection date and time (derived)	15 FEB 2021 14:35
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US3112219

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Collection date (dd MMM yyyy)	15 FEB 2021
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Collection time (00:00 - 23:59)	11:29
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Collection Date and Time (derived)	15 FEB 2021 11:29
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US3112219

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:27

Generated On: 11 Aug 2021 21:50:29

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

US3112219

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	19 MAR 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	OLD29
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US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 08:55
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 10:20
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3112219

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 19 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3112219

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 19 MAR 2021

What was the treatment time? (00:00-23:59) 09:49 (24 HR)

Treatment Date and Time (derived) 19 MAR 2021 09:49

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

US3112219

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:04

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:16:26

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3112219

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:16:26

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112219

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	22 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 APR 2021
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 15:12
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112219

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3112219

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 21:03:08

Generated On: 11 Aug 2021 21:50:29

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

Collection date (dd MMM yyyy)	22 APR 2021
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Collection time (00:00-23:59)	15:20 (24 HR)
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Collection date and time (derived)	22 APR 2021 15:20
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US3112219

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

AEID	USA-US062-2020-MRNA-1273-P30 1000010
Adverse event	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)	16 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)	02 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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EAB) (1725)

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US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT PRESENTED AT TESTING SITE DUE TO SOB CALLED SITE FOR SX'S AND WAS SEEN FOR ILLNESS D1. CONFIRMED POSITIVE ON BOTH SITE AND COUNTY TEST.
Serious Adverse Event Derived (CSA Programming Field Only)	0

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EAB) (1725)

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US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

AEID

Adverse event

SENSITIVITY TO LIGHT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 DEC 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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EAB) (1725)

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 20:25:36

Generated On: 11 Aug 2021 21:50:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

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

Yes ☒

No ☐

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

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Name of Medication Z PACK AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION (COVID-19
DIAGNOSIS)

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication SOB (COVID-19 DIAGNOSIS)

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
EAB) (1725)

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US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication URI (COVID-19 DIAGNOSIS)

Dose per administration 600

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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US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Name of Medication MIRENA INTRAUTERINE
DEVICE

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAUTERINE	
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:16:03

Generated On: 11 Aug 2021 21:50:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 OCT 2020	J TUBE REPLACEMENT	Medical History	

US3112219

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:50:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3112219

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:50:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US062-2020-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US062-2020-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/DEC/2020 15:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US062-2020-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/JAN/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US062-2020-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/JAN/2021 20:30
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

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 21:16:05

Generated On: 11 Aug 2021 21:50:29

SAEID	USA-US062-2020-MRNA-1273-P301000010
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	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/JAN/2021 13:09
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

US3112219 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112219

Form: Participant Creation

Generated On: 11 Aug 2021 21:50:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'US3112219'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:54:18

US3112219

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:39

US3112219

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:54:20

US3112219

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[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 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:39

US3112219

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'SCRN'	System	13 Aug 2020 00:13:39

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered (b) (6) 1988'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:54:20

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '32'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'YEARS'	System	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '32'	System	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Female (F)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'I'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:33

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '12 Aug 2020'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Aug 2020'	System	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2020'	System	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:48

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 22:54:20

US3112219

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:50:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'I'	System	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:50:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	23 Sep 2020 21:19:26
User entered 'No (N)'	(b) (4)	
	Karen Mylerberg (b) (4)	18 Aug 2020 19:24:40
	(b) (4)	

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:21:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:21:43
Data point term sent to Coder	System	23 Sep 2020 21:20:28
User entered 'seasonal allergies'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'UN UNK 1992'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 1992'	System	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '1992'	System	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	23 Sep 2020 21:20:16

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Thyromegaly - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:22:44
Data point term sent to Coder	System	23 Sep 2020 21:21:28
User entered 'thyromegaly'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'UN UNK 2014'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2014'	System	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2014'	System	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	23 Sep 2020 21:20:56

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
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)	29 Dec 2020 19:27:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 19:27:19
Data point term sent to Coder	System	29 Dec 2020 19:26:05
User entered 'obesity'	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2011'	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2011'	System	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2011'	System	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:25:30

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Malnutrition, LLT: Unspecified nutritional deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Dec 2020 07:12:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 07:12:27
Data point term sent to Coder	System	29 Dec 2020 19:27:05
User entered 'Nutritional Deficiency'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2020'	Brenda Grande (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	29 Dec 2020 19:26:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:26:45
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	29 Dec 2020 19:26:27
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Brenda Grande (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2020'	System	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2020'	System	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:26:27

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 19:29:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:29:22
Data point term sent to Coder	System	29 Dec 2020 19:29:06
User entered 'near sighted'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 1997'	Brenda Grande (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Brenda Grande (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 1997'	System	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '1997'	System	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:29:05

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Investigations, HLGt: Cardiac and vascular investigations (excl enzyme tests), HLT: ECG investigations, PT: Electrocardiogram J wave, LLT: J wave - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Dec 2020 12:03:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 12:03:30
Data point term sent to Coder	System	29 Dec 2020 19:31:08
User entered 'J tube'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '01 Jul 2020'	Brenda Grande (b) (4)	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Brenda Grande (b) (4)	29 Dec 2020 19:31:13
User entered 'Yes (Y)'	(b) (4)	
	Brenda Grande (b) (4)	29 Dec 2020 19:30:21
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '09 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brenda Grande (b) (4)	29 Dec 2020 19:31:13
User entered empty.	(b) (4)	
	Brenda Grande (b) (4)	29 Dec 2020 19:30:21
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jul 2020'	System	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2020'	System	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Oct 2020'	System	29 Dec 2020 19:31:13
User entered empty.	System	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2020'	System	29 Dec 2020 19:31:13
User entered empty.	System	29 Dec 2020 19:30:21

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Metabolic surgery, LLT: Bariatric surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 19:39:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 19:39:25
Data point term sent to Coder	System	29 Dec 2020 19:38:14
User entered 'bariatric surgery' reason for change:	Brenda Grande (b) (4)	29 Dec 2020 19:37:15
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	29 Dec 2020 19:32:09
User entered 'j tube replacement'	Brenda Grande (b) (4)	29 Dec 2020 19:31:44
	(b) (4)	

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	29 Dec 2020 19:37:15
User entered '31 Dec 2018' reason for change: Data Entry Error	Brenda Grande (b) (4)	29 Dec 2020 19:37:15
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	29 Dec 2020 19:31:44
User entered '09 Oct 2020'	Brenda Grande (b) (4)	29 Dec 2020 19:31:44
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	29 Dec 2020 19:32:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:32:09
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	29 Dec 2020 19:31:57
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:31:57
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Brenda Grande (b) (4)	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Dec 2018'	System	29 Dec 2020 19:37:15
User entered 'Oct 2020'	System	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2018'	System	29 Dec 2020 19:37:15
User entered '2020'	System	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	29 Dec 2020 19:31:44

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast reduction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Dec 2020 19:39:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:39:26
Data point term sent to Coder	System	29 Dec 2020 19:38:14
User entered 'breast reduction'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2003'	Brenda Grande (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Brenda Grande (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2003'	Brenda Grande (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2003'	System	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2003'	System	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2003'	System	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2003'	System	29 Dec 2020 19:38:14

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 19:40:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 19:40:20
Data point term sent to Coder	System	29 Dec 2020 19:39:15
User entered 'appendectomy'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2002'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2002'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2002'	System	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2002'	System	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2002'	System	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2002'	System	29 Dec 2020 19:39:10

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry, ex. sleep apnea). Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:14:56
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry, ex. sleep apnea). Please verify and update as appropriate. ' answered with 'subject previously had an enlarged turbinate. post procedure no other issues' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 22:18:41
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry, ex. sleep apnea). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 20:08:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Turbinectomy, LLT: Trimming of turbinate bones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:42:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:42:19
Data point term sent to Coder	System	29 Dec 2020 19:41:17
User entered 'turbinate reduction'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2012'	Brenda Grande (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Brenda Grande (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'un UNK 2012'	Brenda Grande (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Brenda Grande (b) (4)	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2012'	System	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2012'	System	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'Jan 2012'	System	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 21:50:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '2012'	System	29 Dec 2020 19:40:51

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '15:32'	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered '12 Aug 2020 15:32'	System	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '61' in	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24
DataPoint set to visible.	System	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '144' lb	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24
DataPoint set to visible.	System	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
Amendment Manager: User entered '27.26545'	System	16 Sep 2020 23:54:37
User entered '27.3'	System	18 Aug 2020 19:25:24
DataPoint set to visible.	System	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'kg/m2'	System	18 Aug 2020 19:25:24
DataPoint set to visible.	System	13 Aug 2020 00:13:52

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Sep 2020 10:06:12
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'data updated per query request' (Site from DM).	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:46:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	23 Sep 2020 20:46:05
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 15:40:16
User entered '98.4' F	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:46:05
User entered 'Oral (Oral)'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:46:05
User entered '79'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'bpm'	System	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:46:05
User entered '14'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'breaths/min'	System	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:46:05
User entered '103'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'mmHg'	System	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Nicolle Mendez (b) (4)	23 Sep 2020 20:46:05
User entered '070'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered 'mmHg'	System	18 Aug 2020 19:25:24

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 11:57:53

US3112219

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53

US3112219

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:25:54

US3112219

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
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)	11 Sep 2020 14:15:36
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:29:19
User entered '12 Aug 2020'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:25:54

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:50:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:26:14

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Urine (URINE)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Negative (NEGATIVE)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
Query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:04:29
User opened query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:39:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	(b) (4) Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42
	(b) (4)	

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User entered empty.	System	18 Aug 2020 19:27:42

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered 'I'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered '0'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:53
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 17:01:05
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:19

US3112219

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:34

US3112219

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:34

US3112219

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:34

US3112219

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'VISIT1'	System	18 Aug 2020 19:28:34

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 23:09:09

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:03:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:03:26
User entered '103692' (non-conformant).	System	12 Aug 2020 23:09:09
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 23:09:09

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:48

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:48

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:48

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:48

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:28:48

US3112219

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:17:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:55:35

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '15:32'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '12 Aug 2020 15:32'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '98.4' F	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '76'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'bpm'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '14'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'breaths/min'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '103'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '070'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:03:23
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).		18 Aug 2020 19:29:55
User entered '17:29'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '12 Aug 2020 17:29'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '97.9' F	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '78'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'bpm'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '14'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'breaths/min'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '104'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '074'	Karen Mylerberg (b) (4)	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	18 Aug 2020 19:29:55

US3112219

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:03

US3112219

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:03

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User closed query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). Query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:49:12
User entered 'No (N)' reason for change: Per Query Resolution	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:14:48
User opened query 'Per CDM: Per CCGs pages 16-17 when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test should be removed from this page. Please update accordingly.' (Site from DM). User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4), (b) (6)	09 Nov 2020 16:14:40 09 Nov 2020 13:58:50
	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty; reason for change Per Query Resolution	(b) (4) Natalie Moy (b) (4)	09 Nov 2020 16:14:40
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty; reason for change Per Query Resolution	(b) (4) Natalie Moy (b) (4)	09 Nov 2020 16:14:40
User entered 'Urine (URINE)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty; reason for change Per Query Resolution	(b) (4) Natalie Moy (b) (4)	09 Nov 2020 16:14:40
User entered 'Negative (NEGATIVE)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:49:14
Query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' answered with 'updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:14:53
User entered 'No (N)' reason for change: Per Query Resolution	Natalie Moy (b) (4) (b) (4)	09 Nov 2020 16:14:40
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:59:39
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered empty.	System	18 Aug 2020 19:30:20

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 00:14:07

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '16:58'	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered '12 Aug 2020 16:58'	System	13 Aug 2020 00:14:07

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Matthew Musikanth	13 Aug 2020 00:14:07
	(b) (4)	

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'ONCE'	System	13 Aug 2020 00:14:07

US3112219

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 00:14:07

US3112219

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:31:49

US3112219

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:31:49

US3112219

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '16:08'	Karen Mylerberg (b) (4)	18 Aug 2020 19:31:49

US3112219

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered '12 Aug 2020 16:08'	System	18 Aug 2020 19:31:49

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '12 Aug 2020'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '15:48'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered '12 Aug 2020 15:48'	System	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered empty.	System	18 Aug 2020 19:32:03

US3112219

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	18 Aug 2020 19:32:09

US3112219

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered '1'	System	18 Aug 2020 19:32:09

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:32:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '741dbe0e-1971-41ff-8f62-6893e29de661'	System	13 Aug 2020 00:32:52
User entered 'Yes (Y)'	System	13 Aug 2020 00:32:52

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:32:41', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '741dbe0e-1971-41ff-8f62-6893e29de661' User entered '97.9'	System	13 Aug 2020 00:32:52
	System	13 Aug 2020 00:32:52

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:32:45', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '741dbe0e-1971-41ff-8f62-6893e29de661'	System	13 Aug 2020 00:32:52
User entered 'No (N)'	System	13 Aug 2020 00:32:52

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:32:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '741dbe0e-1971-41ff-8f62-6893e29de661' User entered '12 Aug 2020 17:32'	System	13 Aug 2020 00:32:52
	System	13 Aug 2020 00:32:52

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 17:18'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 19:48'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:35', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4e8c5e71-87de-4d53-8439-2e06fd4d7001' User entered 'Yes (Y)'	System	13 Aug 2020 03:53:46
	System	13 Aug 2020 03:53:46

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:40', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4e8c5e71-87de-4d53-8439-2e06fd4d7001' User entered '97.6'	System	13 Aug 2020 03:53:46
	System	13 Aug 2020 03:53:46

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:41', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4e8c5e71-87de-4d53-8439-2e06fd4d7001' User entered 'No (N)'	System	13 Aug 2020 03:53:46
	System	13 Aug 2020 03:53:46

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4e8c5e71-87de-4d53-8439-2e06fd4d7001' User entered '12 Aug 2020 20:53'	System	13 Aug 2020 03:53:46
	System	13 Aug 2020 03:53:46

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 20:43'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 2'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '5f640ca8-7867-4a9e-b224-1a4cbf40a81e' User entered 'Yes (Y)'	System	14 Aug 2020 02:25:39
	System	14 Aug 2020 02:25:39

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '5f640ca8-7867-4a9e-b224-1a4cbf40a81e' User entered '95.6'	System	14 Aug 2020 02:25:39
	System	14 Aug 2020 02:25:39

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '5f640ca8-7867-4a9e-b224-1a4cbf40a81e' User entered 'No (N)'	System	14 Aug 2020 02:25:39
	System	14 Aug 2020 02:25:39

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:34', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '5f640ca8-7867-4a9e-b224-1a4cbf40a81e' User entered '13 Aug 2020 21:25'	System	14 Aug 2020 02:25:39
	System	14 Aug 2020 02:25:39

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 3'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:13', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '59d1a1e2-1fbe-4fee-82fe-06f68a255d85'	System	14 Aug 2020 19:03:19
User entered 'No (N)'	System	14 Aug 2020 19:03:19

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '59d1a1e2-1fbe-4fee-82fe-06f68a255d85'	System	14 Aug 2020 19:03:19
User entered 'No (N)'	System	14 Aug 2020 19:03:19

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '59d1a1e2-1fbe-4fee-82fe-06f68a255d85'	System	14 Aug 2020 19:03:19
User entered '14 Aug 2020 14:03'	System	14 Aug 2020 19:03:19

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 4'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1266576a-2f15-4f07-8914-3458af1f878e' User entered 'Yes (Y)'	System	16 Aug 2020 01:12:28
	System	16 Aug 2020 01:12:28

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1266576a-2f15-4f07-8914-3458af1f878e' User entered '95.6'	System	16 Aug 2020 01:12:28
	System	16 Aug 2020 01:12:28

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1266576a-2f15-4f07-8914-3458af1f878e'	System	16 Aug 2020 01:12:28
User entered 'No (N)'	System	16 Aug 2020 01:12:28

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:25', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1266576a-2f15-4f07-8914-3458af1f878e' User entered '15 Aug 2020 20:12'	System	16 Aug 2020 01:12:28
	System	16 Aug 2020 01:12:28

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 5'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:13', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3ae2d308-9cba-49ed-b6b8-fd18df200dcb' User entered 'Yes (Y)'	System	16 Aug 2020 17:00:29
	System	16 Aug 2020 17:00:29

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3ae2d308-9cba-49ed-b6b8-fd18df200dcb' User entered '97.6'	System	16 Aug 2020 17:00:29
	System	16 Aug 2020 17:00:29

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:19', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3ae2d308-9cba-49ed-b6b8-fd18df200dcb' User entered 'No (N)'	System	16 Aug 2020 17:00:29
	System	16 Aug 2020 17:00:29

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:27', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3ae2d308-9cba-49ed-b6b8-fd18df200dcb' User entered '16 Aug 2020 12:00'	System	16 Aug 2020 17:00:29
	System	16 Aug 2020 17:00:29

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 6'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:46:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3452ffd-6dd1-4b51-bc9c-d9ce55565bd5'	System	17 Aug 2020 21:47:03
User entered 'Yes (Y)'	System	17 Aug 2020 21:47:03

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:46:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3452ffd-6dd1-4b51-bc9c-d9ce55565bd5' User entered '97.6'	System	17 Aug 2020 21:47:03
	System	17 Aug 2020 21:47:03

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:46:57', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3452ffd-6dd1-4b51-bc9c-d9ce55565bd5'	System	17 Aug 2020 21:47:03
User entered 'No (N)'	System	17 Aug 2020 21:47:03

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3452ffd-6dd1-4b51-bc9c-d9ce55565bd5'	System	17 Aug 2020 21:47:03
User entered '17 Aug 2020 14:47'	System	17 Aug 2020 21:47:03

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 7'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3e623f90-3188-482d-ba83-1c441e2957d2'	System	19 Aug 2020 13:00:05
User entered 'Yes (Y)'	System	19 Aug 2020 13:00:05

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3e623f90-3188-482d-ba83-1c441e2957d2' User entered '96.4'	System	19 Aug 2020 13:00:05
	System	19 Aug 2020 13:00:05

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:59', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3e623f90-3188-482d-ba83-1c441e2957d2'	System	19 Aug 2020 13:00:05
User entered 'No (N)'	System	19 Aug 2020 13:00:05

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3e623f90-3188-482d-ba83-1c441e2957d2' User entered '19 Aug 2020 06:00'	System	19 Aug 2020 13:00:05
	System	19 Aug 2020 13:00:05

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:33:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3a7e85af-880a-4ebf-bf5e-8c5fb032b9da'	System	13 Aug 2020 00:34:07
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:34:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:33:37', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3a7e85af-880a-4ebf-bf5e-8c5fb032b9da'	System	13 Aug 2020 00:34:07
User entered 'No (N)'	System	13 Aug 2020 00:34:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:33:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3a7e85af-880a-4ebf-bf5e-8c5fb032b9da'	System	13 Aug 2020 00:34:07
User entered 'No (N)'	System	13 Aug 2020 00:34:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:03', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3a7e85af-880a-4ebf-bf5e-8c5fb032b9da'	System	13 Aug 2020 00:34:07
User entered 'None (1)'	System	13 Aug 2020 00:34:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3a7e85af-880a-4ebf-bf5e-8c5fb032b9da' User entered '12 Aug 2020 17:34'	System	13 Aug 2020 00:34:07
	System	13 Aug 2020 00:34:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 17:18'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 19:48'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:47', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'db65506e-96fe-4ce1-bfe2-6be586609dff'	System	13 Aug 2020 03:54:02
User entered 'None (1)'	System	13 Aug 2020 03:54:02

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:49', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'db65506e-96fe-4ce1-bfe2-6be586609dff' User entered 'No (N)'	System	13 Aug 2020 03:54:02
	System	13 Aug 2020 03:54:02

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:51', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'db65506e-96fe-4ce1-bfe2-6be586609dff' User entered 'No (N)'	System	13 Aug 2020 03:54:02
	System	13 Aug 2020 03:54:02

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'db65506e-96fe-4ce1-bfe2-6be586609dff'	System	13 Aug 2020 03:54:02
User entered 'None (1)'	System	13 Aug 2020 03:54:02

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:53:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'db65506e-96fe-4ce1-bfe2-6be586609dff' User entered '12 Aug 2020 20:53'	System	13 Aug 2020 03:54:02
	System	13 Aug 2020 03:54:02

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 20:43'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 2'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9450f18b-9ef6-4293-af11-651e2858542a'	System	14 Aug 2020 02:26:15
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 02:26:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9450f18b-9ef6-4293-af11-651e2858542a' User entered 'No (N)'	System	14 Aug 2020 02:26:15
	System	14 Aug 2020 02:26:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:25:57', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9450f18b-9ef6-4293-af11-651e2858542a' User entered 'No (N)'	System	14 Aug 2020 02:26:15
	System	14 Aug 2020 02:26:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9450f18b-9ef6-4293-af11-651e2858542a' User entered 'None (1)'	System	14 Aug 2020 02:26:15
	System	14 Aug 2020 02:26:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9450f18b-9ef6-4293-af11-651e2858542a' User entered '13 Aug 2020 21:26'	System	14 Aug 2020 02:26:15
	System	14 Aug 2020 02:26:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 3'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b168df5-9a69-40a6-9640-e5bea9719568' User entered 'None (1)'	System	14 Aug 2020 19:04:04
	System	14 Aug 2020 19:04:04

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b168df5-9a69-40a6-9640-e5bea9719568' User entered 'No (N)'	System	14 Aug 2020 19:04:04
	System	14 Aug 2020 19:04:04

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:35', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b168df5-9a69-40a6-9640-e5bea9719568' User entered 'No (N)'	System	14 Aug 2020 19:04:04
	System	14 Aug 2020 19:04:04

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:03:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b168df5-9a69-40a6-9640-e5bea9719568'	System	14 Aug 2020 19:04:04
User entered 'None (1)'	System	14 Aug 2020 19:04:04

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b168df5-9a69-40a6-9640-e5bea9719568' User entered '14 Aug 2020 14:04'	System	14 Aug 2020 19:04:04
	System	14 Aug 2020 19:04:04

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 4'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1b7fbf72-4964-4d01-899b-3d99d65baca3'	System	16 Aug 2020 01:12:43
User entered 'None (1)'	System	16 Aug 2020 01:12:43

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:30', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1b7fbf72-4964-4d01-899b-3d99d65baca3'	System	16 Aug 2020 01:12:43
User entered 'No (N)'	System	16 Aug 2020 01:12:43

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:36', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1b7fbf72-4964-4d01-899b-3d99d65baca3'	System	16 Aug 2020 01:12:43
User entered 'No (N)'	System	16 Aug 2020 01:12:43

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1b7fbf72-4964-4d01-899b-3d99d65baca3'	System	16 Aug 2020 01:12:43
User entered 'None (1)'	System	16 Aug 2020 01:12:43

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1b7fbf72-4964-4d01-899b-3d99d65baca3'	System	16 Aug 2020 01:12:43
User entered '15 Aug 2020 20:12'	System	16 Aug 2020 01:12:43

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 5'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:53', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '668890aa-d645-4afc-94fb-abc6c7497f35'	System	16 Aug 2020 17:01:12
User entered 'None (1)'	System	16 Aug 2020 17:01:12

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:55', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '668890aa-d645-4afc-94fb-abc6c7497f35' User entered 'No (N)'	System	16 Aug 2020 17:01:12
	System	16 Aug 2020 17:01:12

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:00:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '668890aa-d645-4afc-94fb-abc6c7497f35'	System	16 Aug 2020 17:01:12
User entered 'No (N)'	System	16 Aug 2020 17:01:12

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '668890aa-d645-4afc-94fb-abc6c7497f35'	System	16 Aug 2020 17:01:12
User entered 'None (1)'	System	16 Aug 2020 17:01:12

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:08', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '668890aa-d645-4afc-94fb-abc6c7497f35'	System	16 Aug 2020 17:01:12
User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:12

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 6'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:04', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b143069-e43b-466b-9cb2-3be9c6ab549e'	System	17 Aug 2020 21:47:21
User entered 'None (1)'	System	17 Aug 2020 21:47:21

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:06', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b143069-e43b-466b-9cb2-3be9c6ab549e' User entered 'No (N)'	System	17 Aug 2020 21:47:21
	System	17 Aug 2020 21:47:21

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:10', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b143069-e43b-466b-9cb2-3be9c6ab549e' User entered 'No (N)'	System	17 Aug 2020 21:47:21
	System	17 Aug 2020 21:47:21

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b143069-e43b-466b-9cb2-3be9c6ab549e' User entered 'None (1)'	System	17 Aug 2020 21:47:21
	System	17 Aug 2020 21:47:21

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '9b143069-e43b-466b-9cb2-3be9c6ab549e' User entered '17 Aug 2020 14:47'	System	17 Aug 2020 21:47:21
	System	17 Aug 2020 21:47:21

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 7'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:04', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '96f0b3fa-79c3-4405-91a1-bf87158bb42f' User entered 'None (1)'	System	19 Aug 2020 13:00:15
	System	19 Aug 2020 13:00:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:07', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '96f0b3fa-79c3-4405-91a1-bf87158bb42f' User entered 'No (N)'	System	19 Aug 2020 13:00:15
	System	19 Aug 2020 13:00:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '96f0b3fa-79c3-4405-91a1-bf87158bb42f' User entered 'No (N)'	System	19 Aug 2020 13:00:15
	System	19 Aug 2020 13:00:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '96f0b3fa-79c3-4405-91a1-bf87158bb42f' User entered 'None (1)'	System	19 Aug 2020 13:00:15
	System	19 Aug 2020 13:00:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T06:00:14', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '96f0b3fa-79c3-4405-91a1-bf87158bb42f' User entered '19 Aug 2020 06:00'	System	19 Aug 2020 13:00:15
	System	19 Aug 2020 13:00:15

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:14', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'None (0)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'None (0)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'None (0)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187'	System	13 Aug 2020 00:34:42
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:30', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'None (0)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'None (0)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:37', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered 'No (N)'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T17:34:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '99ae0d00-08d5-4c76-9828-05b76d9bf187' User entered '12 Aug 2020 17:34'	System	13 Aug 2020 00:34:42
	System	13 Aug 2020 00:34:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 17:18'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 19:48'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:02', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3' User entered 'None (0)'	System	13 Aug 2020 03:54:42
	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:03', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3' User entered 'None (0)'	System	13 Aug 2020 03:54:42
	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:04', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered 'None (0)'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:07', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered 'None (0)'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:11', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered 'None (0)'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered 'No (N)'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-12T20:54:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '67e97ac2-d106-47b5-af58-22ff5be610c3'	System	13 Aug 2020 03:54:42
User entered '12 Aug 2020 20:54'	System	13 Aug 2020 03:54:42

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Aug 2020 20:43'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 2'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:19', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered 'No interference with activity (1)'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602' User entered 'None (0)'	System	14 Aug 2020 02:26:51
	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:34', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered 'No interference with activity (1)'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:37', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered 'No interference with activity (1)'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:41', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:43', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602' User entered 'None (0)'	System	14 Aug 2020 02:26:51
	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered 'No (N)'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-13T21:26:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c5313afe-acbd-4d76-ba07-8c414d95a602'	System	14 Aug 2020 02:26:51
User entered '13 Aug 2020 21:26'	System	14 Aug 2020 02:26:51

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 3'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:07', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:08', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:11', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:13', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'None (0)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:16', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered 'No (N)'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-14T14:04:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8e700068-26ef-4734-8f60-5d25a23c42e8' User entered '14 Aug 2020 14:04'	System	14 Aug 2020 19:04:56
	System	14 Aug 2020 19:04:56

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 4'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:49', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:51', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:53', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:55', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:12:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3' User entered 'None (0)'	System	16 Aug 2020 01:13:11
	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:13:02', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3'	System	16 Aug 2020 01:13:11
User entered 'No (N)'	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-15T20:13:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '21f82a6b-31b7-493e-b786-6d100166f8f3'	System	16 Aug 2020 01:13:11
User entered '15 Aug 2020 20:13'	System	16 Aug 2020 01:13:11

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 5'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:40', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:41', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:43', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'None (0)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered 'No (N)'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-16T12:01:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7e1037f8-9483-4770-a982-1a3415035ba7' User entered '16 Aug 2020 12:01'	System	16 Aug 2020 17:01:54
	System	16 Aug 2020 17:01:54

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 6'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:27', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:32', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:47:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered 'None (0)'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:55:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0'	System	17 Aug 2020 21:56:01
User entered 'No (N)'	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-17T14:55:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '946e1fc5-ecbd-42de-9c03-adb04ca355f0' User entered '17 Aug 2020 14:55'	System	17 Aug 2020 21:56:01
	System	17 Aug 2020 21:56:01

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 7'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:20', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:25', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:35', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'None (0)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered 'No (N)'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-08-19T05:59:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '733f26f0-62e0-48a7-9002-0e5a595c3059' User entered '19 Aug 2020 05:59'	System	19 Aug 2020 12:59:47
	System	19 Aug 2020 12:59:47

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 00:14:07

US3112219

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:44:10

US3112219

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:44:10

US3112219

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:44:10

US3112219

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:44:10

US3112219

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 23:44:15

US3112219

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	19 Aug 2020 23:44:15

US3112219

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:11:18

US3112219

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:11:18

US3112219

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:11:18

US3112219

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:11:18

US3112219

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 20:11:23

US3112219

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	26 Aug 2020 20:11:23

US3112219

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	09 Sep 2020 20:08:11

US3112219

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered empty.	Karen Mylerberg (b) (4)	09 Sep 2020 20:08:11

US3112219

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered empty.	Karen Mylerberg (b) (4)	09 Sep 2020 20:08:11

US3112219

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered empty.	Karen Mylerberg (b) (4)	09 Sep 2020 20:08:11

US3112219

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:10

US3112219

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	09 Sep 2020 16:29:10

US3112219

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:19

US3112219

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:19

US3112219

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:19

US3112219

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'VISIT2'	System	09 Sep 2020 16:29:19

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '08:20'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Sep 2020 08:20'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '95'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'bpm'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'breaths/min'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '108'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '79'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '09:44'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Sep 2020 09:44'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '99.3' F	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '80'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'bpm'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'breaths/min'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '112'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '68'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	17 Sep 2020 14:40:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 16:38:07
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 14:40:20

US3112219

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	19 Oct 2020 16:38:07
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 14:40:20

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
Query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:04:35
User opened query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:39:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered empty.	System	17 Sep 2020 14:40:49

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9:13'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Sep 2020 9:13'	System	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'ONCE'	System	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 16:29:42

US3112219

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '08:40'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Sep 2020 08:40'	System	17 Sep 2020 14:41:05

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '08:27'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Sep 2020 08:27'	System	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered empty.	System	17 Sep 2020 14:41:22

US3112219

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 16:29:47

US3112219

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '1'	System	09 Sep 2020 16:29:47

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:43:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30ce22db-d44d-4847-910f-0ca461280063' User entered 'Yes (Y)'	System	09 Sep 2020 16:44:09
	System	09 Sep 2020 16:44:09

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:02', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30ce22db-d44d-4847-910f-0ca461280063' User entered '99.3'	System	09 Sep 2020 16:44:09
	System	09 Sep 2020 16:44:09

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:04', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30ce22db-d44d-4847-910f-0ca461280063' User entered 'No (N)'	System	09 Sep 2020 16:44:09
	System	09 Sep 2020 16:44:09

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:06', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30ce22db-d44d-4847-910f-0ca461280063' User entered '09 Sep 2020 09:44'	System	09 Sep 2020 16:44:09
	System	09 Sep 2020 16:44:09

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 09:33'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:03'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6b20dc4f-fc8d-432f-85bf-40e9c1e94a0f' User entered 'Yes (Y)'	System	09 Sep 2020 19:58:25
	System	09 Sep 2020 19:58:25

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:16', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6b20dc4f-fc8d-432f-85bf-40e9c1e94a0f' User entered '98.7'	System	09 Sep 2020 19:58:25
	System	09 Sep 2020 19:58:25

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6b20dc4f-fc8d-432f-85bf-40e9c1e94a0f' User entered 'No (N)'	System	09 Sep 2020 19:58:25
	System	09 Sep 2020 19:58:25

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6b20dc4f-fc8d-432f-85bf-40e9c1e94a0f' User entered '09 Sep 2020 12:58'	System	09 Sep 2020 19:58:25
	System	09 Sep 2020 19:58:25

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:58'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 2'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 3'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:14', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c453fb45-da38-4373-83b8-0118b41e89a8' User entered 'Yes (Y)'	System	12 Sep 2020 01:26:28
	System	12 Sep 2020 01:26:28

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c453fb45-da38-4373-83b8-0118b41e89a8' User entered '96.5'	System	12 Sep 2020 01:26:28
	System	12 Sep 2020 01:26:28

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c453fb45-da38-4373-83b8-0118b41e89a8' User entered 'No (N)'	System	12 Sep 2020 01:26:28
	System	12 Sep 2020 01:26:28

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'c453fb45-da38-4373-83b8-0118b41e89a8' User entered '11 Sep 2020 18:26'	System	12 Sep 2020 01:26:28
	System	12 Sep 2020 01:26:28

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 4'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '462acb85-9ce2-4453-9cf2-1a069c13999a' User entered 'No (N)'	System	12 Sep 2020 19:00:35
	System	12 Sep 2020 19:00:35

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '462acb85-9ce2-4453-9cf2-1a069c13999a' User entered 'No (N)'	System	12 Sep 2020 19:00:35
	System	12 Sep 2020 19:00:35

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '462acb85-9ce2-4453-9cf2-1a069c13999a' User entered '12 Sep 2020 12:00'	System	12 Sep 2020 19:00:35
	System	12 Sep 2020 19:00:35

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 5'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3181e516-3477-4f71-b653-3a3bc101a29c' User entered 'No (N)'	System	14 Sep 2020 16:38:40
	System	14 Sep 2020 16:38:40

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:34', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3181e516-3477-4f71-b653-3a3bc101a29c'	System	14 Sep 2020 16:38:40
User entered 'No (N)'	System	14 Sep 2020 16:38:40

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:37', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '3181e516-3477-4f71-b653-3a3bc101a29c' User entered '14 Sep 2020 09:38'	System	14 Sep 2020 16:38:40
	System	14 Sep 2020 16:38:40

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 6'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:11', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0c153079-133a-462a-be2e-769ac67c3375' User entered 'Yes (Y)'	System	14 Sep 2020 19:00:27
	System	14 Sep 2020 19:00:27

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0c153079-133a-462a-be2e-769ac67c3375' User entered '95.6'	System	14 Sep 2020 19:00:27
	System	14 Sep 2020 19:00:27

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0c153079-133a-462a-be2e-769ac67c3375'	System	14 Sep 2020 19:00:27
User entered 'No (N)'	System	14 Sep 2020 19:00:27

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0c153079-133a-462a-be2e-769ac67c3375' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 19:00:27
	System	14 Sep 2020 19:00:27

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 7'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a35d60c2-34e0-4d9d-9cec-743eed9ea97d' User entered 'Yes (Y)'	System	15 Sep 2020 22:26:49
	System	15 Sep 2020 22:26:49

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:43', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a35d60c2-34e0-4d9d-9cec-743eed9ea97d' User entered '95.5'	System	15 Sep 2020 22:26:49
	System	15 Sep 2020 22:26:49

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a35d60c2-34e0-4d9d-9cec-743eed9ea97d' User entered 'No (N)'	System	15 Sep 2020 22:26:49
	System	15 Sep 2020 22:26:49

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a35d60c2-34e0-4d9d-9cec-743eed9ea97d' User entered '15 Sep 2020 15:26'	System	15 Sep 2020 22:26:49
	System	15 Sep 2020 22:26:49

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b849edfd-0236-43fb-b168-06453f77e39f' User entered 'None (1)'	System	09 Sep 2020 16:44:27
	System	09 Sep 2020 16:44:27

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b849edfd-0236-43fb-b168-06453f77e39f' User entered 'No (N)'	System	09 Sep 2020 16:44:27
	System	09 Sep 2020 16:44:27

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b849edfd-0236-43fb-b168-06453f77e39f' User entered 'No (N)'	System	09 Sep 2020 16:44:27
	System	09 Sep 2020 16:44:27

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b849edfd-0236-43fb-b168-06453f77e39f' User entered 'None (1)'	System	09 Sep 2020 16:44:27
	System	09 Sep 2020 16:44:27

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b849edfd-0236-43fb-b168-06453f77e39f' User entered '09 Sep 2020 09:44'	System	09 Sep 2020 16:44:27
	System	09 Sep 2020 16:44:27

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 09:33'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:03'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:25', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '12018347-640e-4cb3-ba17-96c96e7555e3' User entered 'None (1)'	System	09 Sep 2020 19:58:37
	System	09 Sep 2020 19:58:37

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:27', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '12018347-640e-4cb3-ba17-96c96e7555e3' User entered 'No (N)'	System	09 Sep 2020 19:58:37
	System	09 Sep 2020 19:58:37

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '12018347-640e-4cb3-ba17-96c96e7555e3' User entered 'No (N)'	System	09 Sep 2020 19:58:37
	System	09 Sep 2020 19:58:37

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '12018347-640e-4cb3-ba17-96c96e7555e3' User entered 'None (1)'	System	09 Sep 2020 19:58:37
	System	09 Sep 2020 19:58:37

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '12018347-640e-4cb3-ba17-96c96e7555e3' User entered '09 Sep 2020 12:58'	System	09 Sep 2020 19:58:37
	System	09 Sep 2020 19:58:37

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:58'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 2'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 3'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:30', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'fab4fa6d-fa83-432f-ba1c-2580e6e48efc'	System	12 Sep 2020 01:26:45
User entered 'None (1)'	System	12 Sep 2020 01:26:45

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'fab4fa6d-fa83-432f-ba1c-2580e6e48efc'	System	12 Sep 2020 01:26:45
User entered 'No (N)'	System	12 Sep 2020 01:26:45

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:35', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'fab4fa6d-fa83-432f-ba1c-2580e6e48efc'	System	12 Sep 2020 01:26:45
User entered 'No (N)'	System	12 Sep 2020 01:26:45

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'fab4fa6d-fa83-432f-ba1c-2580e6e48efc'	System	12 Sep 2020 01:26:45
User entered 'None (1)'	System	12 Sep 2020 01:26:45

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:41', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'fab4fa6d-fa83-432f-ba1c-2580e6e48efc'	System	12 Sep 2020 01:26:45
User entered '11 Sep 2020 18:26'	System	12 Sep 2020 01:26:45

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 4'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3318ea8-29c3-4f32-b397-75d288b8c7ea' User entered 'None (1)'	System	12 Sep 2020 19:01:09
	System	12 Sep 2020 19:01:09

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:53', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3318ea8-29c3-4f32-b397-75d288b8c7ea' User entered 'No (N)'	System	12 Sep 2020 19:01:09
	System	12 Sep 2020 19:01:09

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3318ea8-29c3-4f32-b397-75d288b8c7ea' User entered 'No (N)'	System	12 Sep 2020 19:01:09
	System	12 Sep 2020 19:01:09

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:00:59', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3318ea8-29c3-4f32-b397-75d288b8c7ea' User entered 'None (1)'	System	12 Sep 2020 19:01:09
	System	12 Sep 2020 19:01:09

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:03', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'f3318ea8-29c3-4f32-b397-75d288b8c7ea' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 19:01:09
	System	12 Sep 2020 19:01:09

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 5'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:40', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cc265f98-72c7-4b61-8cda-81a98d671933'	System	14 Sep 2020 16:38:48
User entered 'None (1)'	System	14 Sep 2020 16:38:48

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cc265f98-72c7-4b61-8cda-81a98d671933'	System	14 Sep 2020 16:38:48
User entered 'No (N)'	System	14 Sep 2020 16:38:48

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:43', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cc265f98-72c7-4b61-8cda-81a98d671933'	System	14 Sep 2020 16:38:48
User entered 'No (N)'	System	14 Sep 2020 16:38:48

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cc265f98-72c7-4b61-8cda-81a98d671933'	System	14 Sep 2020 16:38:48
User entered 'None (1)'	System	14 Sep 2020 16:38:48

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cc265f98-72c7-4b61-8cda-81a98d671933'	System	14 Sep 2020 16:38:48
User entered '14 Sep 2020 09:38'	System	14 Sep 2020 16:38:48

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 6'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6fd5720f-dec1-4457-b1a8-927fdbf3df8f' User entered 'None (1)'	System	14 Sep 2020 19:00:46
	System	14 Sep 2020 19:00:46

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:26', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6fd5720f-dec1-4457-b1a8-927fdbf3df8f' User entered 'No (N)'	System	14 Sep 2020 19:00:46
	System	14 Sep 2020 19:00:46

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6fd5720f-dec1-4457-b1a8-927fdbf3df8f' User entered 'No (N)'	System	14 Sep 2020 19:00:46
	System	14 Sep 2020 19:00:46

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:37', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6fd5720f-dec1-4457-b1a8-927fdbf3df8f' User entered 'None (1)'	System	14 Sep 2020 19:00:46
	System	14 Sep 2020 19:00:46

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6fd5720f-dec1-4457-b1a8-927fdbf3df8f' User entered '14 Sep 2020 12:00'	System	14 Sep 2020 19:00:46
	System	14 Sep 2020 19:00:46

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 7'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b56b1b3f-60fd-4126-9018-d24e88e26a54'	System	15 Sep 2020 22:27:07
User entered 'None (1)'	System	15 Sep 2020 22:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b56b1b3f-60fd-4126-9018-d24e88e26a54'	System	15 Sep 2020 22:27:07
User entered 'No (N)'	System	15 Sep 2020 22:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:26:59', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b56b1b3f-60fd-4126-9018-d24e88e26a54' User entered 'No (N)'	System	15 Sep 2020 22:27:07
	System	15 Sep 2020 22:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b56b1b3f-60fd-4126-9018-d24e88e26a54'	System	15 Sep 2020 22:27:07
User entered 'None (1)'	System	15 Sep 2020 22:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:02', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b56b1b3f-60fd-4126-9018-d24e88e26a54' User entered '15 Sep 2020 15:27'	System	15 Sep 2020 22:27:07
	System	15 Sep 2020 22:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:26', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:27', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:29', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:30', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:32', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'None (0)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered 'No (N)'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T09:44:36', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '71a496b4-8550-414f-93b1-541974756f5f' User entered '09 Sep 2020 09:44'	System	09 Sep 2020 16:44:39
	System	09 Sep 2020 16:44:39

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 09:33'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:03'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:36', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:38', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:39', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:40', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:43', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered 'None (0)'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:45', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063'	System	09 Sep 2020 19:58:52
User entered 'No (N)'	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-09T12:58:47', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '4fbb1b22-463a-4d38-ad0a-8ef73f5ba063' User entered '09 Sep 2020 12:58'	System	09 Sep 2020 19:58:52
	System	09 Sep 2020 19:58:52

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '09 Sep 2020 12:58'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 2'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 3'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:51', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:53', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:55', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:57', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:26:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered 'None (0)'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:27:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79'	System	12 Sep 2020 01:27:07
User entered 'No (N)'	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-11T18:27:04', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'beff79ee-d1b7-46ed-8bea-e8e02c534a79' User entered '11 Sep 2020 18:27'	System	12 Sep 2020 01:27:07
	System	12 Sep 2020 01:27:07

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 4'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:19', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83' User entered 'None (0)'	System	12 Sep 2020 19:01:37
	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83' User entered 'None (0)'	System	12 Sep 2020 19:01:37
	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:22', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83' User entered 'None (0)'	System	12 Sep 2020 19:01:37
	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83' User entered 'None (0)'	System	12 Sep 2020 19:01:37
	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:26', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83' User entered 'None (0)'	System	12 Sep 2020 19:01:37
	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83'	System	12 Sep 2020 19:01:37
User entered 'None (0)'	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:30', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83'	System	12 Sep 2020 19:01:37
User entered 'No (N)'	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-12T12:01:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '2263df09-1940-4922-ae57-0253e9ea8e83'	System	12 Sep 2020 19:01:37
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 19:01:37

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 5'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:49', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:51', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:53', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'None (0)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered 'No (N)'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T09:38:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad400a4d-7673-4a70-a604-f630965e08cf' User entered '14 Sep 2020 09:38'	System	14 Sep 2020 16:39:01
	System	14 Sep 2020 16:39:01

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 6'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:45', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:47', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:49', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97' User entered 'None (0)'	System	14 Sep 2020 19:00:55
	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:51', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97'	System	14 Sep 2020 19:00:55
User entered 'No (N)'	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-14T12:00:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8c46b3c6-1d51-4c06-9ec7-5e4cd461cb97'	System	14 Sep 2020 19:00:55
User entered '14 Sep 2020 12:00'	System	14 Sep 2020 19:00:55

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	09 Sep 2020 16:29:42
User entered 'Day 7'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:06', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:07', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:10', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'None (0)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:14', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered 'No (N)'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-09-15T15:27:16', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '30f0e0c2-6819-4623-b470-a557b900509a' User entered '15 Sep 2020 15:27'	System	15 Sep 2020 22:27:19
	System	15 Sep 2020 22:27:19

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 16:29:42

US3112219

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:50:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 16:29:42

US3112219

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 00:32:14

US3112219

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 00:32:14

US3112219

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 00:32:14

US3112219

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 00:32:14

US3112219

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:44:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 00:32:19

US3112219

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	17 Sep 2020 00:32:19

US3112219

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:21:47

US3112219

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '23 Sep 2020'	Karen Mylerberg (b) (4)	23 Sep 2020 21:21:47

US3112219

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:21:47

US3112219

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	23 Sep 2020 21:21:47

US3112219

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Sep 2020 21:21:55

US3112219

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	23 Sep 2020 21:21:55

US3112219

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 22:10:29

US3112219

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '30 Sep 2020'	Karen Mylerberg (b) (4)	30 Sep 2020 22:10:29

US3112219

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	30 Sep 2020 22:10:29

US3112219

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 22:10:29

US3112219

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 22:10:36

US3112219

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	30 Sep 2020 22:10:36

US3112219

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 20:45:05

US3112219

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 20:45:05

US3112219

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	13 Oct 2020 20:45:05

US3112219

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'VISIT3'	System	13 Oct 2020 20:45:05

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:47:27
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 20:47:27
User entered '7:52' reason for change: Data Entry Error	Natalie Moy (b) (4)	13 Oct 2020 20:47:27
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 20:47:11
User entered empty.	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Oct 2020 7:52'	System	13 Oct 2020 20:47:27
User entered empty.	System	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '97.8' F	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '82'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'bpm'	System	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '16'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'breaths/min'	System	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '108'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '68'	Natalie Moy (b) (4)	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered 'mmHg'	System	13 Oct 2020 20:47:11

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42

US3112219

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42

US3112219

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'No (N)'	Natalie Moy (b) (4)	13 Oct 2020 20:47:54

US3112219

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered empty.	Natalie Moy (b) (4)	13 Oct 2020 20:47:54

US3112219

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 20:48:34

US3112219

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '9 Oct 2020'	Natalie Moy (b) (4)	13 Oct 2020 20:48:34

US3112219

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered '7:56'	Natalie Moy (b) (4)	13 Oct 2020 20:48:34

US3112219

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '9 Oct 2020 7:56'	System	13 Oct 2020 20:48:34

US3112219

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:06:22
User entered 'Yes (Y)'	Natalie Moy (b) (4)	13 Oct 2020 20:48:40

US3112219

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:42
User entered '1'	System	13 Oct 2020 20:48:40

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 64'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-12T11:03:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b930f0c4-2e2a-4039-8398-785b7498522a' User entered 'No (N)'	System	12 Oct 2020 18:03:11
	System	12 Oct 2020 18:03:11

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-12T11:03:06', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b930f0c4-2e2a-4039-8398-785b7498522a'	System	12 Oct 2020 18:03:11
User entered 'No (N)'	System	12 Oct 2020 18:03:11

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-12T11:03:09', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b930f0c4-2e2a-4039-8398-785b7498522a' User entered '12 Oct 2020 11:03:09'	System	12 Oct 2020 18:03:11
	System	12 Oct 2020 18:03:11

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '12 Oct 2020 00:01'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '16 Oct 2020 23:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 71'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-20T11:01:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07bf84c8-d9b1-4c06-b3e3-f190b6213745'	System	20 Oct 2020 18:01:10
User entered 'No (N)'	System	20 Oct 2020 18:01:10

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-20T11:01:05', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07bf84c8-d9b1-4c06-b3e3-f190b6213745'	System	20 Oct 2020 18:01:10
User entered 'No (N)'	System	20 Oct 2020 18:01:10

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-20T11:01:08', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07bf84c8-d9b1-4c06-b3e3-f190b6213745' User entered '20 Oct 2020 11:01:08'	System	20 Oct 2020 18:01:10
	System	20 Oct 2020 18:01:10

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '19 Oct 2020 00:01'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '23 Oct 2020 23:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 78'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-26T07:29:08', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b3247ee9-b2ef-4faf-9bca-5e80f07c2e70'	System	26 Oct 2020 14:29:16
User entered 'No (N)'	System	26 Oct 2020 14:29:16

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-26T07:29:11', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b3247ee9-b2ef-4faf-9bca-5e80f07c2e70'	System	26 Oct 2020 14:29:16
User entered 'No (N)'	System	26 Oct 2020 14:29:16

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-10-26T07:29:14', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'b3247ee9-b2ef-4faf-9bca-5e80f07c2e70' User entered '26 Oct 2020 07:29:14'	System	26 Oct 2020 14:29:16
	System	26 Oct 2020 14:29:16

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '26 Oct 2020 00:01'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '30 Oct 2020 23:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 92'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-11-09T08:18:57', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '475e3bfc-a6b8-4f63-8285-187d2349a830' User entered 'No (N)'	System	09 Nov 2020 16:19:07
	System	09 Nov 2020 16:19:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-11-09T08:19:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '475e3bfc-a6b8-4f63-8285-187d2349a830'	System	09 Nov 2020 16:19:07
User entered 'No (N)'	System	09 Nov 2020 16:19:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C3E1C7E-5AFD-461C-8D70-4605DC3C766E)', Time: '2020-11-09T08:19:03', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '475e3bfc-a6b8-4f63-8285-187d2349a830' User entered '09 Nov 2020 08:19:03'	System	09 Nov 2020 16:19:07
	System	09 Nov 2020 16:19:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '09 Nov 2020 00:01'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 23:02:30
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '13 Nov 2020 23:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04
Data entry locked.	System	13 Aug 2020 00:14:07
User entered 'Day 99'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '16 Nov 2020 00:01'	System	13 Aug 2020 00:14:07

US3112219

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 05:37:04
Data entry locked.	System	13 Aug 2020 00:14:07
User entered '20 Nov 2020 23:59'	System	13 Aug 2020 00:14:07

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-01T15:11:17', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cedab3cc-75c4-444f-a808-718bee7c342d' User entered 'No (N)'	System	01 Dec 2020 23:11:27
	System	01 Dec 2020 23:11:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-01T15:11:20', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cedab3cc-75c4-444f-a808-718bee7c342d' User entered 'No (N)'	System	01 Dec 2020 23:11:27
	System	01 Dec 2020 23:11:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-01T15:11:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'cedab3cc-75c4-444f-a808-718bee7c342d' User entered '01 Dec 2020 15:11:24'	System	01 Dec 2020 23:11:27
	System	01 Dec 2020 23:11:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-05T09:27:49', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'adb204a5-406b-4503-b7cd-2c48aaffc0ad' User entered 'No (N)'	System	05 Dec 2020 17:30:43
	System	05 Dec 2020 17:30:43

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-05T09:30:34', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'adb204a5-406b-4503-b7cd-2c48aaffc0ad' User entered 'No (N)'	System	05 Dec 2020 17:30:43
	System	05 Dec 2020 17:30:43

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-05T09:30:38', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'adb204a5-406b-4503-b7cd-2c48aaffc0ad' User entered '05 Dec 2020 09:30:38'	System	05 Dec 2020 17:30:43
	System	05 Dec 2020 17:30:43

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-13T10:26:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd8fff071-586d-4b27-88dd-3a6b3bde4f1b'	System	13 Dec 2020 18:26:53
User entered 'No (N)'	System	13 Dec 2020 18:26:53

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-13T10:26:45', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd8fff071-586d-4b27-88dd-3a6b3bde4f1b'	System	13 Dec 2020 18:26:53
User entered 'No (N)'	System	13 Dec 2020 18:26:53

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-13T10:26:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd8fff071-586d-4b27-88dd-3a6b3bde4f1b' User entered '13 Dec 2020 10:26:50'	System	13 Dec 2020 18:26:53
	System	13 Dec 2020 18:26:53

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered 'Yes (Y)'	System	21 Dec 2020 16:58:05
	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:15', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered 'Yes (Y)'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered 'Yes (Y)'	System	21 Dec 2020 16:58:05
	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered '1'	System	21 Dec 2020 16:58:05
	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '1'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:44', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered '0'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:46', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:50', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered 'Yes (Y)'	System	21 Dec 2020 16:58:05
	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7'	System	21 Dec 2020 16:58:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-21T08:57:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '600f235d-2e85-429e-a0dc-e1c9b21aa1c7' User entered '21 Dec 2020 08:57:54'	System	21 Dec 2020 16:58:05
	System	21 Dec 2020 16:58:05

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-27T12:00:16', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd5b5425b-a0b8-45e1-93ed-3aa50003b510' User entered 'No (N)'	System	27 Dec 2020 20:00:35
	System	27 Dec 2020 20:00:35

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-27T12:00:19', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd5b5425b-a0b8-45e1-93ed-3aa50003b510'	System	27 Dec 2020 20:00:35
User entered 'Yes (Y)'	System	27 Dec 2020 20:00:35

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-27T12:00:22', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd5b5425b-a0b8-45e1-93ed-3aa50003b510'	System	27 Dec 2020 20:00:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 20:00:35

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2020-12-27T12:00:24', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'd5b5425b-a0b8-45e1-93ed-3aa50003b510' User entered '27 Dec 2020 12:00:24'	System	27 Dec 2020 20:00:35
	System	27 Dec 2020 20:00:35

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-02T13:46:12', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a208c980-3873-4fe1-851b-2c0a673fc1f0' User entered 'No (N)'	System	02 Jan 2021 21:46:33
	System	02 Jan 2021 21:46:33

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-02T13:46:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a208c980-3873-4fe1-851b-2c0a673fc1f0'	System	02 Jan 2021 21:46:33
User entered 'Yes (Y)'	System	02 Jan 2021 21:46:33

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-02T13:46:20', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a208c980-3873-4fe1-851b-2c0a673fc1f0'	System	02 Jan 2021 21:46:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 21:46:33

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-02T13:46:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'a208c980-3873-4fe1-851b-2c0a673fc1f0' User entered '02 Jan 2021 13:46:23'	System	02 Jan 2021 21:46:33

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-10T15:15:23', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e2fec841-230a-4e6b-998b-dd7ed4e1dc0c'	System	10 Jan 2021 23:15:37
User entered 'No (N)'	System	10 Jan 2021 23:15:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-10T15:15:27', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e2fec841-230a-4e6b-998b-dd7ed4e1dc0c'	System	10 Jan 2021 23:15:37
User entered 'No (N)'	System	10 Jan 2021 23:15:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (408589DD-CB20-4ADE-8F11-162FB692CE97)', Time: '2021-01-10T15:15:33', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e2fec841-230a-4e6b-998b-dd7ed4e1dc0c' User entered '10 Jan 2021 15:15:33'	System	10 Jan 2021 23:15:37
	System	10 Jan 2021 23:15:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-08T20:06:52', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ea6da388-d5a9-4efd-a60b-081cf1f45b18'	System	09 Feb 2021 04:07:01
User entered 'No (N)'	System	09 Feb 2021 04:07:01

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-08T20:06:54', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ea6da388-d5a9-4efd-a60b-081cf1f45b18'	System	09 Feb 2021 04:07:01
User entered 'No (N)'	System	09 Feb 2021 04:07:01

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-08T20:06:56', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ea6da388-d5a9-4efd-a60b-081cf1f45b18'	System	09 Feb 2021 04:07:01
User entered '08 Feb 2021 20:06:56'	System	09 Feb 2021 04:07:01

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-12T08:01:26', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1a892553-ab7c-4a6e-8b35-d1f9b32bd4c1' User entered 'No (N)'	System	12 Feb 2021 16:01:37
	System	12 Feb 2021 16:01:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-12T08:01:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1a892553-ab7c-4a6e-8b35-d1f9b32bd4c1' User entered 'No (N)'	System	12 Feb 2021 16:01:37
	System	12 Feb 2021 16:01:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-12T08:01:31', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '1a892553-ab7c-4a6e-8b35-d1f9b32bd4c1' User entered '12 Feb 2021 08:01:31'	System	12 Feb 2021 16:01:37
	System	12 Feb 2021 16:01:37

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:34:42', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed' User entered 'Yes (Y)'	System	20 Feb 2021 06:35:10
	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:34:45', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed' User entered 'No (N)'	System	20 Feb 2021 06:35:10
	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:34:48', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed' User entered 'No (N)'	System	20 Feb 2021 06:35:10
	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:34:55', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed' User entered 'Yes (Y)'	System	20 Feb 2021 06:35:10
	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:34:58', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed'	System	20 Feb 2021 06:35:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-02-19T22:35:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '035e856e-3559-4ce2-9750-862b9a7924ed' User entered '19 Feb 2021 22:35:00'	System	20 Feb 2021 06:35:10
	System	20 Feb 2021 06:35:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-01T17:59:25', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad51a78e-03ce-4df2-9ff5-22ad9a877d15'	System	02 Mar 2021 02:00:54
User entered 'No (N)'	System	02 Mar 2021 02:00:54

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-01T17:59:26', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad51a78e-03ce-4df2-9ff5-22ad9a877d15'	System	02 Mar 2021 02:00:54
User entered 'No (N)'	System	02 Mar 2021 02:00:54

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-01T17:59:28', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ad51a78e-03ce-4df2-9ff5-22ad9a877d15'	System	02 Mar 2021 02:00:54
User entered '01 Mar 2021 17:59:28'	System	02 Mar 2021 02:00:54

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-05T20:34:59', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0f50a70c-4904-4346-ba81-0c588b01e288'	System	06 Mar 2021 04:43:10
User entered 'No (N)'	System	06 Mar 2021 04:43:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-05T20:35:01', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0f50a70c-4904-4346-ba81-0c588b01e288'	System	06 Mar 2021 04:43:10
User entered 'Yes (Y)'	System	06 Mar 2021 04:43:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-05T20:35:03', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0f50a70c-4904-4346-ba81-0c588b01e288'	System	06 Mar 2021 04:43:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 04:43:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-05T20:35:06', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '0f50a70c-4904-4346-ba81-0c588b01e288' User entered '05 Mar 2021 20:35:06'	System	06 Mar 2021 04:43:10
	System	06 Mar 2021 04:43:10

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-13T16:05:16-08:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ab67aa65-6aed-4df3-a578-3615d3ec492d'	System	14 Mar 2021 00:07:16
User entered 'No (N)'	System	14 Mar 2021 00:07:16

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-13T16:05:18-08:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ab67aa65-6aed-4df3-a578-3615d3ec492d'	System	14 Mar 2021 00:07:16
User entered 'No (N)'	System	14 Mar 2021 00:07:16

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-13T16:05:20-08:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'ab67aa65-6aed-4df3-a578-3615d3ec492d'	System	14 Mar 2021 00:07:16
User entered '13 Mar 2021 16:05:20'	System	14 Mar 2021 00:07:16

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-19T09:07:05-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8ae2fd62-600b-4289-bb4a-fbab74962ec1' User entered 'No (N)'	System	19 Mar 2021 16:12:47
	System	19 Mar 2021 16:12:47

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-19T09:07:08-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8ae2fd62-600b-4289-bb4a-fbab74962ec1' User entered 'No (N)'	System	19 Mar 2021 16:12:47

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-19T09:07:12-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '8ae2fd62-600b-4289-bb4a-fbab74962ec1' User entered '19 Mar 2021 09:07:12'	System	19 Mar 2021 16:12:47
	System	19 Mar 2021 16:12:47

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-26T12:34:18-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '024e6526-279b-44c9-bdb2-28ea26c427ef' User entered 'No (N)'	System	26 Mar 2021 19:34:26
	System	26 Mar 2021 19:34:26

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-26T12:34:20-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '024e6526-279b-44c9-bdb2-28ea26c427ef'	System	26 Mar 2021 19:34:26
User entered 'No (N)'	System	26 Mar 2021 19:34:26

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-26T12:34:22-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '024e6526-279b-44c9-bdb2-28ea26c427ef' User entered '26 Mar 2021 12:34:22'	System	26 Mar 2021 19:34:26
	System	26 Mar 2021 19:34:26

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-04T12:00:15-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7432ed9f-9167-4d19-8a4c-49f7eab747b5' User entered 'No (N)'	System	04 Apr 2021 19:00:25
	System	04 Apr 2021 19:00:25

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-04T12:00:17-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7432ed9f-9167-4d19-8a4c-49f7eab747b5'	System	04 Apr 2021 19:00:25
User entered 'No (N)'	System	04 Apr 2021 19:00:25

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-04T12:00:21-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7432ed9f-9167-4d19-8a4c-49f7eab747b5' User entered '04 Apr 2021 12:00:21'	System	04 Apr 2021 19:00:25
	System	04 Apr 2021 19:00:25

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-11T06:53:22-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '39cb7ae4-08b7-4421-a1f6-31c69ff45010'	System	11 Apr 2021 13:53:27
User entered 'No (N)'	System	11 Apr 2021 13:53:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-11T06:53:23-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '39cb7ae4-08b7-4421-a1f6-31c69ff45010'	System	11 Apr 2021 13:53:27
User entered 'No (N)'	System	11 Apr 2021 13:53:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-11T06:53:25-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '39cb7ae4-08b7-4421-a1f6-31c69ff45010'	System	11 Apr 2021 13:53:27
User entered '11 Apr 2021 06:53:25'	System	11 Apr 2021 13:53:27

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-19T17:59:25-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e65ed23d-de1e-407e-a6e2-d459c7ee9771' User entered 'No (N)'	System	20 Apr 2021 01:00:06

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-19T17:59:27-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e65ed23d-de1e-407e-a6e2-d459c7ee9771' User entered 'No (N)'	System	20 Apr 2021 01:00:06

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-19T17:59:29-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: 'e65ed23d-de1e-407e-a6e2-d459c7ee9771' User entered '19 Apr 2021 17:59:29'	System	20 Apr 2021 01:00:06
	System	20 Apr 2021 01:00:06

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-23T22:04:16-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07519749-69e3-4edc-bf30-9b6b57d29095'	System	28 Apr 2021 23:13:17
User entered 'No (N)'	System	28 Apr 2021 23:13:17

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-23T22:04:17-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07519749-69e3-4edc-bf30-9b6b57d29095'	System	28 Apr 2021 23:13:17
User entered 'No (N)'	System	28 Apr 2021 23:13:17

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-04-23T22:04:19-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '07519749-69e3-4edc-bf30-9b6b57d29095'	System	28 Apr 2021 23:13:17
User entered '23 Apr 2021 22:04:19'	System	28 Apr 2021 23:13:17

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-05-02T12:00:17-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7ef62342-4689-4213-95c0-349ea0bcaded'	System	02 May 2021 19:00:30
User entered 'No (N)'	System	02 May 2021 19:00:30

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-05-02T12:00:20-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7ef62342-4689-4213-95c0-349ea0bcaded'	System	02 May 2021 19:00:30
User entered 'No (N)'	System	02 May 2021 19:00:30

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-05-02T12:00:23-07:00', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '7ef62342-4689-4213-95c0-349ea0bcaded'	System	02 May 2021 19:00:30
User entered '02 May 2021 12:00:23'	System	02 May 2021 19:00:30

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:37:04

US3112219

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:37:04
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:37:04

US3112219

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:50:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-01T17:59:18', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6acf26f4-eda1-4dc2-a9c0-0b4dbe6e481c'	System	02 Mar 2021 02:00:48
User entered 'No (N)'	System	02 Mar 2021 02:00:48

US3112219

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:50:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:09:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C6DB4B-13E7-4270-B5DC-A07BE2464360)', Time: '2021-03-01T17:59:21', User OID: 'PatientReportedOutcome (US3112219)', ODM File OID: '6acf26f4-eda1-4dc2-a9c0-0b4dbe6e481c' User entered '01 Mar 2021 17:59:21'	System	02 Mar 2021 02:00:48
	System	02 Mar 2021 02:00:48

US3112219

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:36

US3112219

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:51:02
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:36

US3112219

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:51:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:36

US3112219

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:51:02
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:36

US3112219

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:51:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:41

US3112219

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:36:22
User entered 'I'	System	04 Nov 2020 18:46:41

US3112219

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:13:01

US3112219

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '08 Dec 2020'	Matthew Musikanth (b) (4)	09 Dec 2020 00:13:01

US3112219

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:13:01

US3112219

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Matthew Musikanth (b) (4)	09 Dec 2020 00:13:01

US3112219

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	09 Dec 2020 00:12:53

US3112219

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'I'	System	09 Dec 2020 00:12:53

US3112219

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:03:47
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:03:47
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:01:50
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:01:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:01:50
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	08 Feb 2021 23:41:13
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:13

US3112219

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:13

US3112219

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:03:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:13

US3112219

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Call not made due to subject being in illness phase'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:13

US3112219

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:20

US3112219

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'I'	System	08 Feb 2021 23:41:20

US3112219

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:53

US3112219

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '8 Feb 2021'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:53

US3112219

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:53

US3112219

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:41:53

US3112219

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:42:01

US3112219

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'I'	System	08 Feb 2021 23:42:01

US3112219

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User closed query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 19 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:20:40
Query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 19 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:33:43
User opened query 'Per CDM: Visit 4 Day 209 and OL-D29 are both dated 19 Mar 2021. However, the data on the Vital signs forms at one visit is recorded and the other visit is blank. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 16:03:14
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:25:53

US3112219

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:25:53

US3112219

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:25:53

US3112219

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'VISIT4'	System	22 Mar 2021 17:25:53

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '08:55'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered '19 Mar 2021 08:55'	System	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '97.9' F	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '75'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'bpm'	System	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '16'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'breaths/min'	System	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '102'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'mmHg'	System	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '72'	Brenda Grande (b) (4) (b) (4)	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'mmHg'	System	29 Mar 2021 15:09:51

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08

US3112219

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08

US3112219

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:24

US3112219

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:24

US3112219

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:38

US3112219

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '19 Mar 2021'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:38

US3112219

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered '09:40'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:38

US3112219

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered '19 Mar 2021 09:40'	System	22 Mar 2021 17:26:38

US3112219

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:27
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:26:42

US3112219

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:41:08
User entered 'I'	System	22 Mar 2021 17:26:42

US3112219

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:08:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 23:43:26

US3112219

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:08:18
	(b) (4)	
User entered '7 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 23:43:26

US3112219

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:08:18
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Apr 2021 23:43:26

US3112219

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:08:18
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 23:43:26

US3112219

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User signature succeeded.	Todd Simmons (b) (4)	09 Apr 2021 00:08:18
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 23:44:22

US3112219

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:59
User entered 'I'	System	08 Apr 2021 23:44:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:02:14
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:02:14
User entered '10:33'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '16 Dec 2020 10:33'	System	17 Dec 2020 00:20:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:02:14
User entered 'Safety Call (Safety Call)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:50:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:02:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 1 (Day 1)'	Matthew Musikanth	17 Dec 2020 00:20:50
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered '0'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered '100' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:36:03
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per ETRTR: Temperature is registered within Illness Visit Day 1 Folder. Please consider updating answer, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:32:07
	(b) (4), (b) (6)	06 Jan 2021 23:50:51
Query 'Per ETRTR: Temperature is registered within Illness Visit Day 1 Folder. Please consider updating answer, thanks.' answered with 'has been updated ' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:36:15
User entered '98.9' F reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:36:03
User opened query 'Per ETRTR: Temperature is registered within Illness Visit Day 1 Folder. Please consider updating answer, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 22:27:11
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:50:51
User entered 'None (None)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:20:50

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 2 (Day 2)'	Matthew Musikanth	18 Dec 2020 00:13:10
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered '17 Dec 2020'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered '0'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered '91'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered '100.4' F	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Moderate (Moderate)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:00:42
User entered 'None (None)'	Matthew Musikanth (b) (4)	18 Dec 2020 00:13:10

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 3 (Day 3)'	Brenda Grande (b) (4)	29 Dec 2020 17:58:24
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered '18 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered '100' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:00:40
User entered '91'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered '99.1' F reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:00:40
User entered '100.4' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:00:40
User entered 'Moderate (Moderate)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:00:40
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:00:40
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:01:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 17:58:24

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 4 (Day 4)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered '19 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered '97'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered '98.7' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:25:27
User closed query 'Please clarify. Source does not indicate mild for runny nose. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:25:25
Query 'Please clarify. Source does not indicate mild for runny nose. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:28:20
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:28:01
User entered 'None (None)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:28:01
User opened query 'Please clarify. Source does not indicate mild for runny nose. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:06:32
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:05:19
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:04:04

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 5 (Day 5)'	Brenda Grande (b) (4)	29 Dec 2020 18:06:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered '20 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered '97'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered '98.9' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:26:14
User closed query 'Please clarify. Source indicates no new loss of smell. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:26:12
Query 'Please clarify. Source indicates no new loss of smell. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:27:27
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:27:15
User entered 'None (None)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:27:15
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User opened query 'Please clarify. Source indicates no new loss of smell. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:09:35
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:09:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:06:02

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 6 (Day 6)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered '21 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered '96'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered '99.8' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:10:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:08:26

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 7 (Day 7)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered '22 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered '99'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered '99.6' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:26:40
User closed query 'Please clarify. Source indicates mild congestion. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:26:39
Query 'Please clarify. Source indicates mild congestion. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:51
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:45
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:45
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User opened query 'Please clarify. Source indicates mild congestion. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:26:58
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:27:06
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:09:59

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 8 (Day 8)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered '23 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered '99'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered '96.6' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:27:04
User closed query 'Please clarify. Source indicates congestion mild. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:27:01
Query 'Please clarify. Source indicates congestion mild. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:31
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:26:25
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User opened query 'Please clarify. Source indicates congestion mild. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:28:50
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:00
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:12:53

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 9 (Day 9)'	Brenda Grande (b) (4)	29 Dec 2020 18:14:07
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered '24 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered '98'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered '98.9' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:29:55
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:07

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 10 (Day 10)'	Brenda Grande (b) (4)	29 Dec 2020 18:14:54
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered '25 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered 'I'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered empty.	System	29 Dec 2020 18:14:54

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:32:35
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:14:54

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 11 (Day 11)'	Brenda Grande (b) (4)	29 Dec 2020 18:16:22
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered '26 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered '100'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered '97.7' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:27:33
User closed query 'Please clarify. Source indicates No new lost of smell. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:27:30
Query 'Please clarify. Source indicates No new lost of smell. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:55
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:49
User entered 'None (None)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:49
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User opened query 'Please clarify. Source indicates No new lost of smell. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:33:55
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:34:05
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:16:22

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 12 (Day 12)'	Brenda Grande (b) (4)	29 Dec 2020 18:17:55
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered '27 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered '100'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:17:55

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered '99.1' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:27:52
User closed query 'Please clarify. Source indicated No chills. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:27:51
Query 'Please clarify. Source indicated No chills. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:21
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:11
User entered 'None (None)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:25:11
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User opened query 'Please clarify. Source indicated No chills. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:41:21
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:18:23
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:42:01
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:17:55

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Day 13 (Day 13)'	Brenda Grande (b) (4)	29 Dec 2020 18:20:15
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered '28 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered '97'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered '98.2' F	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 00:44:46
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:20:15

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:42
User entered 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per CDM: Day 13 Date is 28DEC2020 and Day 14 Date is 30DEC2020. Please confirm if this date is correct. If not, please reconcile or else clarify missing dates.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:06:34
Query 'Per CDM: Day 13 Date is 28DEC2020 and Day 14 Date is 30DEC2020. Please confirm if this date is correct. If not, please reconcile or else clarify missing dates.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:51
User opened query 'Per CDM: Day 13 Date is 28DEC2020 and Day 14 Date is 30DEC2020. Please confirm if this date is correct. If not, please reconcile or else clarify missing dates.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 21:15:28
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
Query 'Please clarify. Day 14 source dated 29Dec2020 indicates it was not completed as subject was unable to be contacted. Please confirm and update as necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 18:35:58
User opened query 'Please clarify. Day 14 source dated 29Dec2020 indicates it was not completed as subject was unable to be contacted. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 00:46:52
User entered '30 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered '0'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered '100'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered '99' F	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'Mild (Mild)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:36:48
User entered 'None (None)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:05:39

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:42
User entered 'Day 15 (Day 15)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered '31 Dec 2020'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered '0'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered '98'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered '98.8' F	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'Mild (Mild)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 23:28:24
User closed query 'Please clarify. Source indicates None. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 23:28:21
Query 'Please clarify. Source indicates None. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	07 Jan 2021 20:24:43
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:21:56
User entered 'None (None)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:21:56
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User opened query 'Please clarify. Source indicates None. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 18:43:49
User entered 'Not Done (Not Done)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:44:03
User entered 'None (None)'	Natalie Moy (b) (4) (b) (4)	01 Jan 2021 00:28:44

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:42
User entered 'Day 16 (Day 16)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered '1 Jan 2021'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered '0'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered '98'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered '98.8' F	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'Mild (Mild)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:45:31
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:35:19

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:42
User entered 'Day 17 (Day 17)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered '2 Jan 2021'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered '0'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered '99'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered '98.9' F	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:46:45
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 19:36:06

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per CDM: Symptom Day 18 is missing. Please confirm if this log line should be Day 28 and whether or not the date is correct.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 06:14:17
Query 'Per CDM: Symptom Day 18 is missing. Please confirm if this log line should be Day 28 and whether or not the date is correct.' answered with 'Day 18 has been added to symptom log this symptom day should be Day 29' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:34:16
User entered 'Day 29 (Day 29)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:32:24
User opened query 'Per CDM: Symptom Day 18 is missing. Please confirm if this log line should be Day 28 and whether or not the date is correct.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 21:17:06
User entered 'Day 28 (Day 28)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered '13 Jan 2021'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered '0'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered '99'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered '%'	System	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered '98.6' F	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:33:52
User entered 'None (None)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:46:00

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User closed query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 16 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:18:30
Query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 16 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' answered with 'no sxs reported for 29DEC2020. Data originally entered is correct ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	20 Apr 2021 21:26:15
User opened query 'Per CDM: Please verify that Symptom Log Line 19 in Covid-19 Assessment 16 Dec 2020 has symptoms in source. If so, please complete all the missing symptoms. If not, please delete all symptoms from this Symptom Log Line and keep Assessment Not Done box ticked. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 13:04:56
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Day 14 (Day 14)'	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '29 Dec 2020'	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User closed query 'Per CDM: Assessment Not Done is ticked however O2 Saturation and Temperature has data recorded. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 21:05:54
Query 'Per CDM: Assessment Not Done is ticked however O2 Saturation and Temperature has data recorded. Please reconcile.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	21 Apr 2021 18:11:49
User opened query 'Per CDM: Assessment Not Done is ticked however O2 Saturation and Temperature has data recorded. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 17:19:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'I'	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:44
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:03:08
	(b) (4)	
DataPoint Un-verified.	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
Signature has been broken.	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	16 Mar 2021 15:30:17
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
User entered empty.	System	21 Apr 2021 18:11:27
User entered '%'	System	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 21:05:47
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:03:08
	(b) (4)	
DataPoint Un-verified.	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
Signature has been broken.	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Matthew Musikanth	21 Apr 2021 18:11:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered missing code ND - Not Done.	Brenda Grande (b) (4)	16 Mar 2021 15:30:17
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 21:50:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:47:08
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:23:08
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	16 Mar 2021 15:30:17

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered '16 Dec 2020'	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered 'Yes (Y)'	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:50:29

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 19:15:43
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 04:38:45
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 'Conf. Positive' (Site from System).	Matthew Musikanth (b) (4)	21 Dec 2020 22:01:38
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	21 Dec 2020 21:59:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	21 Dec 2020 21:59:19
Query 'Data is required. Please complete.' answered with 'Pending' (Site from System).	Matthew Musikanth (b) (4)	17 Dec 2020 00:21:14
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 00:21:10
User entered empty.	Matthew Musikanth (b) (4)	17 Dec 2020 00:21:10

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

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[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered '16 Dec 2020'	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

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[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: COVID Diagnostic Test

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered empty.	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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Form: COVID Diagnostic Test

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[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered 'No (N)'	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered empty.	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 23:48:37
User entered empty.	Matthew Musikanth	17 Dec 2020 00:21:10
	(b) (4)	

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:32
User entered 'I'	System	21 Dec 2020 21:59:19

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

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Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:27
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:41
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:44
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:45
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:39
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:50
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:51
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:45:53
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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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)	30 Apr 2021 03:18:26
	(b) (4)	
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User closed query 'Per source, Day 2 Illness visit O2 saturation is 91%. Please confirm and update response to EDC. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 23:17:39
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:17:36
Query 'Per source, Day 2 Illness visit O2 saturation is 91%. Please confirm and update response to EDC. ' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	04 Feb 2021 22:44:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 22:44:14
User opened query 'Per source, Day 2 Illness visit O2 saturation is 91%. Please confirm and update response to EDC. ' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 20:53:28
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:02:02

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:17:41
User entered '17 Dec 2020' reason for change: Data Entry Error	Matthew Musikanth	04 Feb 2021 22:44:14
	(b) (4)	
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:17:42
User entered '17 Dec 2020' reason for change: Data Entry Error	Matthew Musikanth	04 Feb 2021 22:44:14
	(b) (4)	
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 23:17:45
User entered '91' reason for change: Data Entry Error	Matthew Musikanth	04 Feb 2021 22:44:14
	(b) (4)	
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:49:36
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:49:38
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:49:39
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:49:41
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:12
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:14
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:15
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:17
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:20
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:22
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:24
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:26
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:28
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:30
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:31
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:33
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:35
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:37
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:38
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:40
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:50:43
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:27
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:46
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

Evidence of Shock Requires
Vasopressors

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:47
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:51
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:53
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:54
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:57
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:51:58
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:00
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:02
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:03
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:09
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:11
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:13
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:14
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:17
User entered 'No (N)'	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:18
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:50:29

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:26
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:52:21
User entered empty.	Matthew Musikanth	21 Dec 2020 22:02:02
	(b) (4)	

US3112219

Folder: Covid-19 Assessment 16 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:50:29

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:18:20
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:21:02
User entered 'No (N)'	Matthew Musikanth	18 Feb 2021 19:03:08
	(b) (4)	

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 3 (Day 3)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:56:57
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:56:57
User entered '18 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 5 (Day 5)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:00
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:00
User entered '20 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 7 (Day 7)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:05
User entered '22 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 9 (Day 9)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:08
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:08
User entered '24 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 14 (Day 14)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:11
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 30DEC2020 is reported in PPD central lab with 29DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 08:15:00
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:56:29
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 30DEC2020 is reported in PPD central lab with 29DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'sample was taken the 29th but collected on the 30th. updated edc. thank youy' (Site from DM).	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:01:07
User entered '29 Dec 2020' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	28 Jan 2021 16:00:48
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 30DEC2020 is reported in PPD central lab with 29DEC2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:19:05
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:24:59
User entered '30 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:24:59
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 20:57:11
User entered '29 Dec 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:32:31
User entered '30 Dec 2020'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 21 (Day 21)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:38:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:31:00
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:38:18
User entered '5 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:31:00
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User accepted default value 'Day 28 (Day 28)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:57:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:32:25
User entered 'No (N)'	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:57:29
User entered '13 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 16:32:25
User entered empty.	Matthew Musikanth (b) (4)	31 Dec 2020 17:02:40

US3112219

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit Day 3, 20DEC2020 is reported under Illness Visit Day 5 and also 22DEC2020 is reported under Illness Visit Day 7 in PPD Central lab, however they are missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Jan 2021 11:01:03
	(b) (4), (b) (6)	07 Jan 2021 18:54:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit Day 3, 20DEC2020 is reported under Illness Visit Day 5 and also 22DEC2020 is reported under Illness Visit Day 7 in PPD Central lab, however they are missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:40:55
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18DEC2020 is reported under Illness Visit Day 3, 20DEC2020 is reported under Illness Visit Day 5 and also 22DEC2020 is reported under Illness Visit Day 7 in PPD Central lab, however they are missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Matthew Musikanth (b) (4)	30 Dec 2020 09:57:31 17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:54:18
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:54:18
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'SICKD1'	System	17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '11:40'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered '16 Dec 2020 11:40'	System	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25
DataPoint set to visible.	System	17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25
DataPoint set to visible.	System	17 Dec 2020 00:22:10

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '98.9' F	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered empty.	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '82'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'bpm'	System	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '16'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'breaths/min'	System	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '118'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:56:47
User entered '68'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	17 Dec 2020 00:26:25

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

US3112219

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

US3112219

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:57:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:32

US3112219

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:57:06
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:32

US3112219

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:50:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:57:18
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:42

US3112219

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per Lab Recon: SARS-COV2: PPD GCL has a record of SARS sample collected under Illness visit Day 1, however sample collection date is missing in PPD GCL. Please kindly review Preclarus PPD portal, and update the missing sample collection date in PPD GCL records.Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:20:08
Query 'Per Lab Recon: SARS-COV2: PPD GCL has a record of SARS sample collected under Illness visit Day 1, however sample collection date is missing in PPD GCL. Please kindly review Preclarus PPD portal, and update the missing sample collection date in PPD GCL records.Thank you. ' answered with 'Preclarus PPD portal has all samples as 16DEC2020' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 19:47:36
User opened query 'Per Lab Recon: SARS-COV2: PPD GCL has a record of SARS sample collected under Illness visit Day 1, however sample collection date is missing in PPD GCL. Please kindly review Preclarus PPD portal, and update the missing sample collection date in PPD GCL records.Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 08:10:16
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:57:18
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	17 Dec 2020 00:26:42

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:45:01
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:45:01
User entered '13 Jan 2021'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:45:01
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'SICKD28'	System	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '13 Jan 2021'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 23:44:36
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Jan 2021 23:44:36
User entered '17:58' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:44:36
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Jan 2021 23:42:37
User entered empty.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered '13 Jan 2021 17:58'	System	21 Jan 2021 23:44:36
User entered empty.	System	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37
DataPoint set to visible.	System	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37
DataPoint set to visible.	System	21 Jan 2021 23:40:22

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '98.6' F	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered empty.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '82'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'bpm'	System	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '16'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'breaths/min'	System	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '124'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	18 Feb 2021 18:26:38
User entered '82'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User entered 'mmHg'	System	21 Jan 2021 23:42:37

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:55:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:44:52

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:55:11
User entered '13 Jan 2021'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:44:52

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:50:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:55:34
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:45:21

US3112219

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:50:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:24
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 06:28:58
	(b) (4), (b) (6)	04 Feb 2021 21:55:34
Query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'yes, site the site had scan in barcodes through Preclarus, accession number 1F636663376. The samples have been shipped shipment tracking number was not obtained but specimen received statement shows ppd received it on 22JAN2021.' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Feb 2021 19:35:54
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). User entered '13 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 09:08:55
	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:45:21

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:20:22

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is reported as 15FEB2021 in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:29:03
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is reported as 15FEB2021 in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'this is the correct visit date, will have lab amend this. thank you' (Site from DM).	Natalie Moy (b) (4) (b) (4)	26 Feb 2021 17:13:27
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is reported as 15FEB2021 in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:14:29
User entered '15 Feb 2021'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:20:22

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	16 Feb 2021 00:20:22
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'UNBLND_DECIDE'	System	16 Feb 2021 00:20:22

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '6 Jan 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:20:46
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:23

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:26:23

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:20:46
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	16 Feb 2021 00:20:46
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	16 Feb 2021 00:20:46
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Placebo (Placebo)'	Natalie Moy (b) (4)	16 Feb 2021 00:20:46
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '1'	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:50:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'I'	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered empty.	System	16 Feb 2021 00:21:44
DataPoint set to visible.	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered empty.	System	16 Feb 2021 00:21:44
DataPoint set to visible.	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '14:16'	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '15 Feb 2021 14:16'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '98.1' F	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '90'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'bpm'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '16'	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'breaths/min'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '104'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'mmHg'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '63'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'mmHg'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered missing code ND - Not Done.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered empty.	System	16 Feb 2021 00:21:44
DataPoint set to visible.	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15:22'	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '15 Feb 2021 15:22'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '99' F	Natalie Moy (b) (4)	16 Feb 2021 00:21:44
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '92'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'bpm'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '16'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'breaths/min'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '112'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'mmHg'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '68'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'mmHg'	System	16 Feb 2021 00:21:44

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:21:50

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:21:50
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:20

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:22:20
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Urine (URINE)'	Natalie Moy (b) (4)	16 Feb 2021 00:22:20
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Natalie Moy (b) (4)	16 Feb 2021 00:22:20
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:04:42
User opened query 'Per CDM: Pregnancy test was performed however, Was FSH sample collected is No. Kindly review and reconcile or provide explanation.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 16:39:52
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:20

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:20

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	16 Feb 2021 00:22:20
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered empty.	System	16 Feb 2021 00:22:20

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	16 Feb 2021 00:22:33
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Natalie Moy (b) (4)	16 Feb 2021 00:22:33
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'mRNA-1273'	System	16 Feb 2021 00:22:33
DataPoint set to visible.	System	16 Feb 2021 00:20:46

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '15 Feb 2021'	Natalie Moy (b) (4)	16 Feb 2021 00:22:33
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '14:51'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '15 Feb 2021 14:51'	System	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Right Arm (RIGHT ARM)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'ONCE'	System	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 00:22:33

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:45

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 16 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:37:05
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 16 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' answered with 'both preclarus and EDC currently have the correct date for OL-1 which is 15FEB2021' (Site from DM).	Brenda Grande (b) (4) (b) (4)	04 Mar 2021 17:21:31
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 16 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:14:39

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 17 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' canceled (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:10:07
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 17 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:09:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 16 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' canceled (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:08:56
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15 FEB 2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is reported under Participant Decision Visit OL-D1/OL-1 Visit with date 16 FEB 2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:08:47

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:08:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'accession# 1F650391263 tracking#936270998928' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 20:08:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 15FEB2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:28:10
User entered '15 Feb 2021'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:45

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '14:35'	Natalie Moy (b) (4)	16 Feb 2021 00:22:45
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '15 Feb 2021 14:35'	System	16 Feb 2021 00:22:45

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	16 Feb 2021 00:22:53

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:38:17
Comment added 'traking#9394742866616'.	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 20:08:23
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' answered with 'accession# 1F650391263 tracking#936270998928' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Mar 2021 20:07:11
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, however please provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:16:23
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 15FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:16:23
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 15FEB2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'tracking number 9394 7428 6616' (Site from DM).	Natalie Moy (b) (4) (b) (4)	26 Feb 2021 17:14:03

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '11:29'	Natalie Moy (b) (4)	16 Feb 2021 00:22:53
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:50:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '15 Feb 2021 11:29'	System	16 Feb 2021 00:22:53

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	16 Feb 2021 00:23:34
	(b) (4)	

US3112219

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:08:29
User entered '1'	System	16 Feb 2021 00:23:34

US3112219

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Feb 2021 19:32:20
	(b) (4)	

US3112219

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered '22 Feb 2021'	Brenda Grande (b) (4)	22 Feb 2021 19:32:20
	(b) (4)	

US3112219

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	22 Feb 2021 19:32:20
	(b) (4)	

US3112219

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Feb 2021 19:32:20
	(b) (4)	

US3112219

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Feb 2021 19:32:25
	(b) (4)	

US3112219

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User entered 'I'	System	22 Feb 2021 19:32:25

US3112219

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User entered 'I'	System	22 Feb 2021 19:32:25
DataPoint set to visible.	System	22 Feb 2021 19:32:25

US3112219

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:15:09
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:15:09
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4)	22 Mar 2021 17:15:09
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'OLD29'	System	22 Mar 2021 17:15:09

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '08:55'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered '19 Mar 2021 08:55'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '97.9' F	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '75'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'bpm'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '16'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'breaths/min'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '102'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'mmHg'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '72'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'mmHg'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '10:20'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered '19 Mar 2021 10:20'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '98.7' F	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '72'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'bpm'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '16'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'breaths/min'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '110'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'mmHg'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '72'	Brenda Grande (b) (4)	22 Mar 2021 17:17:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'mmHg'	System	22 Mar 2021 17:17:38

US3112219

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:18:59
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:18:59
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Urine (URINE)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'No (N)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:19:10
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered empty.	System	22 Mar 2021 17:19:10

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'mRNA-1273'	System	22 Mar 2021 17:19:33
DataPoint set to visible.	System	22 Feb 2021 19:32:25

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '19 Mar 2021'	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered '09:49'	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered '19 Mar 2021 09:49'	System	22 Mar 2021 17:19:33

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:33
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'ONCE'	System	22 Mar 2021 17:19:33

US3112219

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 17:19:33

US3112219

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	22 Mar 2021 17:19:38
	(b) (4)	

US3112219

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:50
User entered 'I'	System	22 Mar 2021 17:19:38

US3112219

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 15:08:54
	(b) (4)	

US3112219

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered '26 Mar 2021'	Brenda Grande (b) (4)	29 Mar 2021 15:08:54
	(b) (4)	

US3112219

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	29 Mar 2021 15:08:54
	(b) (4)	

US3112219

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered empty.	Brenda Grande (b) (4)	29 Mar 2021 15:08:54
	(b) (4)	

US3112219

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:27
	(b) (4)	
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 15:08:48
	(b) (4)	

US3112219

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:48:58
User entered 'I'	System	29 Mar 2021 15:08:48

US3112219

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 22:58:07

US3112219

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '22 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 22:58:07

US3112219

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 22:58:07

US3112219

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:50:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	22 Apr 2021 22:58:07

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '22 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '15:12'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 15:12'	System	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '98.6' F	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '82'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '16'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '100'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '75'	(b) (4), (b) (6)	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:50:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 22:58:54

US3112219

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 22:59:32

US3112219

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 22:59:32

US3112219

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 22:59:17

US3112219

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '22 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 22:59:17

US3112219

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	23 Apr 2021 21:03:08
User entered '15:20'	(b) (4), (b) (6)	22 Apr 2021 22:59:17

US3112219

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 15:20'	System	22 Apr 2021 22:59:17

US3112219

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User closed query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:20:53
Query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'subject states it was reported in error' (Site from DM).	Brenda Grande (b) (4) (b) (4)	01 Apr 2021 19:15:17
User opened query 'Per DM CLR: Per Day 194 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 06:01:43
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
User closed query 'Source listed sensitivity to light during the convalescent period. Please add to EDC' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 21:40:43
Query 'Source listed sensitivity to light during the convalescent period. Please add to EDC' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 20:01:27

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Source listed sensitivity to light during the convalescent period. Please add to EDC' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:06:38
	(b) (4), (b) (6)	22 Dec 2020 00:12:06
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Dec 2020 21:59:28

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:18
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:27:00
User entered 'USA-US062-2020-mRNA-1273-P301000010'	System	22 Dec 2020 15:21:56
User entered 'New'	(b) (4), (b) (6)	22 Dec 2020 15:21:56

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:31:39
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 23:48:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 23:48:09
Data point term sent to Coder	System	21 Jan 2021 23:47:44
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:47:36
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:47:36
User entered 'COVID-19' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 23:47:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:01:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 22:01:47
Data point term sent to Coder	System	21 Dec 2020 22:01:02
User entered 'COvid-19 Diagnosis'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '16 Dec 2020'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:31:44
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:20:09
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	07 Jan 2021 20:20:09
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:05:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 01:30:19
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Matthew Musikanth	07 Jan 2021 20:20:15
	(b) (4)	
DataPoint Un-verified.	Matthew Musikanth	07 Jan 2021 20:20:09
	(b) (4)	
User entered '02 Jan 2021' reason for change: Data Entry Error	Matthew Musikanth	07 Jan 2021 20:20:09
	(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)	30 Dec 2020 22:00:57
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth	21 Dec 2020 22:00:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

US3112219

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:18:05
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:08:07
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:53:35
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'none' (Site from Safety).	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:49:20
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:04:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:51:17
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:02:10
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	31 Dec 2020 17:10:27
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 22:00:37
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'I'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered '0'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:05:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 01:30:14
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 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	07 Jan 2021 20:20:19
DataPoint Un-verified.	Matthew Musikanth (b) (4)	07 Jan 2021 20:20:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Matthew Musikanth (b) (4)	07 Jan 2021 20:20:09
Data Entry Error		
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)	30 Dec 2020 22:01:12
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:05:15
User closed query 'PV Query: Please provide COVID symptom log for 29 Dec 2020. If not obtained, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 18:08:10
DataPoint Un-verified.	Brenda Grande (b) (4)	21 Jan 2021 23:57:42
	(b) (4)	
User entered 'subject presented at testing site due to SOB called site for sx's and was seen for illness D1. confirmed positive on both site and county test.'	Brenda Grande (b) (4)	21 Jan 2021 23:57:42
reason for change: Data Entry Error	(b) (4)	
Query 'PV Query: Please provide COVID symptom log for 29 Dec 2020. If not obtained, please state so.'	Brenda Grande (b) (4)	21 Jan 2021 19:48:53
answered with 'COVID symptom log for 29 Dec 2020 was not obtained' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please provide COVID symptom log for 29 Dec 2020. If not obtained, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 18:04:26
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 Jan 2021 16:02:12
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 'updated conmeds' (Site from Safety).	Matthew Musikanth (b) (4)	31 Dec 2020 17:10:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 22:01:26
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 00:13:09
User entered empty.	Matthew Musikanth (b) (4)	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Dec 2020 22:00:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User coded data point as SOC: Eye disorders, HLGT: Ocular sensory symptoms NEC, HLT: Ocular sensation disorders, PT: Photophobia, LLT: Light sensitivity to eye - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 00:29:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 00:29:33
Data point term sent to Coder	System	04 Feb 2021 23:41:08
User entered 'Sensitivity to Light'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Yes (Y)'	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
User closed query 'Source listed start date of 27Dec2020. Please update EDC' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Mar 2021 16:29:22 16 Mar 2021 16:29:20
Query 'Source listed start date of 27Dec2020. Please update EDC' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:31:31
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		09 Mar 2021 21:31:17
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	09 Mar 2021 21:31:17
User entered '27 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:31:17
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	09 Mar 2021 21:30:36
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		09 Mar 2021 21:30:36
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:30:36
User entered '27 Jan 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:30:36
User opened query 'Source listed start date of 27Dec2020. Please update EDC' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:09:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '27 Jan 2021'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User entered empty.	System	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
User closed query 'Source listed end date of 29Dec2020. Please update EDC. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Mar 2021 16:29:30 16 Mar 2021 16:29:28
Query 'Source listed end date of 29Dec2020. Please update EDC. ' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:31:35
User entered '29 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:31:17
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:30:36
User entered '29 Jan 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	09 Mar 2021 21:30:36
User opened query 'Source listed end date of 29Dec2020. Please update EDC. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 18:10:28 03 Mar 2021 18:07:55
User entered '29 Jan 2021'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User entered empty.	System	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'No (N)'	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:25:36
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth	04 Feb 2021 23:40:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'I'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:25:36
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:07:55
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 23:40:27

US3112219

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User entered '0'	System	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45
User entered 'I'	System	04 Feb 2021 23:40:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:50:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:22:49
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 17:01:45

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PACK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:56:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 05:56:13
Data point term sent to Coder	System	21 Jan 2021 19:53:13
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:28
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PACK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:58:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Jan 2021 18:58:43
Data point term sent to Coder	System	06 Jan 2021 18:40:06
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:40:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX Z-PACK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:02:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:02:21
Data point term sent to Coder	System	29 Dec 2020 18:25:07
User entered 'z pack azithromycin'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Per ETRTR: Please consider using complete term for indications instead of the abbreviations, thanks.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 00:59:22
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:07:51
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:28
User entered 'UPPER RESPIRATORY INFECTION (COVID-19 DIAGNOSIS)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:28
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
Query 'Per ETRTR: Please consider using complete term for indications instead of the abbreviations, thanks.' answered with 'has been updated ' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:40:17
User entered 'Upper Respiratory Infection' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	06 Jan 2021 18:40:04
User opened query 'Per ETRTR: Please consider using complete term for indications instead of the abbreviations, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Jan 2021 22:20:22
User entered 'URI'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered '250'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'mg (mg)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'once daily (QD)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'Oral (ORAL)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered '17 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:08:01
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:50:52
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:50:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User closed query 'Please verify stop date for Z-Pak.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:54:44
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:42
Query 'Please verify stop date for Z-Pak.' answered with 'updated' (Site from CRA).	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:29
User entered '20 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:49:46
User opened query 'Please verify stop date for Z-Pak.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 22:09:25
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:50:52
User entered '2 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:50:52
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:07:15
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User entered '1'	System	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User entered '1'	System	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:11
User entered '804 (804)'	System	29 Dec 2020 18:25:05

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 23:36:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 23:36:08
Data point term sent to Coder	System	21 Jan 2021 19:52:12
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:30:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:30:20
Data point term sent to Coder	System	29 Dec 2020 18:29:10
User entered 'albuterol'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:22
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:06
User entered 'SOB (COVID-19 DIAGNOSIS)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:52:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'SOB'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered '2'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'puff (PUFF)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'as needed (PRN)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'Oral (ORAL)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered '16 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered '16 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:02
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User entered empty.	System	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User entered empty.	System	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:15
User entered empty.	System	29 Dec 2020 18:29:09

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:53:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:53:06
Data point term sent to Coder	System	21 Jan 2021 19:52:12
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:32:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 18:32:19
Data point term sent to Coder	System	29 Dec 2020 18:32:12
User entered 'Mucinex'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 22:10:03
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:48
User entered 'URI (COVID-19 DIAGNOSIS)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:48
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'URI'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 20:29:28
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:19
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:04
User entered '600' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:04
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 04:30:26
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered '1'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:57:16
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:04
User entered 'mg (mg)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:04
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'tablet (TABLET)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'as needed (PRN)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'Oral (ORAL)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered '17 Dec 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered '0'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:18
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:17
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:17
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:19
User entered '31 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	05 Feb 2021 18:52:04
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:17
User entered '02 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	21 Jan 2021 19:51:17
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:09:28
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User entered empty.	System	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User entered empty.	System	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:27:18
User entered empty.	System	29 Dec 2020 18:31:36

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 21:16:06
	(b) (4)	
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 00:04:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 00:04:42
	(b) (4)	
Data point term sent to Coder	System	08 Feb 2021 23:48:58
User entered 'Mirena intrauterine device'	Karen Mylerberg (b) (4)	08 Feb 2021 23:48:20
	(b) (4)	

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'contraception'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '20'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'ug (ug)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Other (OTHER)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Intrauterine'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '02 Feb 2021'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Feb 2021 23:48:20

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:50:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:42:41

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 21:50:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered '09 Oct 2020'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:43:28

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 21:50:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'j tube replacement'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:43:28

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered 'Medical History (MH)'	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:43:28

US3112219

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 21:50:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
User entered empty.	Brenda Grande (b) (4) (b) (4)	29 Dec 2020 19:43:28

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'USA-US062-2020-MRNA-1273-P301000010'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Laurie'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Han-Conrad'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '9040 Friars Rd St 540'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'San Diego'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'CA'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '92108'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'US'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Jan 2021 18:09:21
User entered '3'	System	08 Jan 2021 01:30:59
User entered '2'	System	05 Jan 2021 16:02:35
User entered '1'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'USA-US062-2020-MRNA-1273-P301000010'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Laurie'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Han-Conrad'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '9040 Friars Rd St 540'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'San Diego'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'CA'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '92108'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'US'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Jan 2021 18:09:21
User entered '3'	System	08 Jan 2021 01:30:59
User entered '2'	System	05 Jan 2021 16:02:35
User entered '1'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:50:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered '22/Dec/2020 15:23'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:50:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'USA-US062-2020-MRNA-1273-P301000010'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Laurie'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Han-Conrad'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '9040 Friars Rd St 540'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'San Diego'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'CA'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '92108'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'US'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Jan 2021 18:09:21
User entered '3'	System	08 Jan 2021 01:30:59
User entered '2'	System	05 Jan 2021 16:02:35
User entered '1'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:50:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
User entered '05/Jan/2021 11:02'	System	05 Jan 2021 16:02:35

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:50:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Jan 2021 01:30:42
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 16:02:35

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'USA-US062-2020-MRNA-1273-P301000010'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Laurie'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Han-Conrad'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '9040 Friars Rd St 540'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'San Diego'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'CA'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '92108'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'US'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Jan 2021 18:09:21
User entered '3'	System	08 Jan 2021 01:30:59
User entered '2'	System	05 Jan 2021 16:02:35
User entered '1'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:50:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
User entered '07/Jan/2021 20:30'	System	08 Jan 2021 01:30:59

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:50:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
User entered 'I'	(b) (4), (b) (6)	08 Jan 2021 01:30:59

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'USA-US062-2020-MRNA-1273-P301000010'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'No (N)'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Laurie'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'Han-Conrad'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '9040 Friars Rd St 540'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'San Diego'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered 'CA'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 15:23:04
User entered '92108'	System	22 Dec 2020 15:21:56

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 16:02:27
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 19:26:28
User entered 'US'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 11 Aug 2021 21:50:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Jan 2021 18:09:21
User entered '3'	System	08 Jan 2021 01:30:59
User entered '2'	System	05 Jan 2021 16:02:35
User entered '1'	System	22 Dec 2020 15:23:27

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:50:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
User entered '22/Jan/2021 13:09'	System	22 Jan 2021 18:09:21

US3112219

Folder: SAE USA-US062-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:50:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:16:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:46:45
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 18:09:21